



The significance of health and well-being protection in the European risk assessment

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Thesis submitted for assessment with a view to obtaining the degree of
Master in Comparative, European and International Laws (LL.M.)
of the European University Institute

Florence, 30 April 2015

European University Institute

Department of Law

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0. Introduction

This thesis examines how much importance the European Union¹ attaches to consumer safety in different settings of risk assessment and explores the reasons for the varying regulation regimes. It analyses the value of health and well-being protection vs. the value of the European Single market in two cases from practice, of which one dealt with dangerous vehicle lifts (non-foodstuff) and the other one with contaminated sprouts (foodstuff). Moreover, by comparing both plus their legal bases, it confronts the internal market driven risk management of non-foodstuff risks with the significantly more safety driven management of foodstuff risks and seeks to probe the causes for the differing approaches. In particular, it investigates the predisposition of foodstuff to be treated as so-called ‘emergencies’—in principle, a state of exception in the assessment of risks.

More precisely, the present study seeks to show firstly that on EU level, the protection of the *health and well-being of consumers mainly serves as a mean for the establishment of the internal market* and that secondly, in contrast to non-foodstuff risk, *foodstuff risks are usually treated as emergencies*, meaning that *after* their occurrence, risk regulators exhaust all protection measures considered to be just barely tolerable for the (internal) market.

In *AGM-COS.MET v Suomen valito/Tanno Lehtinen*,² disobeying the instructions of his superior, a Finnish official, in 2000, warned publicly against a risk-posing type of vehicle lift; the affected lift producer eventually sought to hold the official and the Finnish state responsible for the consequent damage. In interpreting the rules on the free movement of goods and on the conditions of liability for infringement of Community law, the ECJ ruled that when issuing the warning, Finland infringed the safeguard procedures provided by the applicable Machinery Directive; in particular, the official’s utterances were attributable to the Finnish State. The Court moreover dismissed any justification for a warning on grounds of health protection outside the procedures laid down in the Directive. In the end, the parties reached a settlement; the Finnish official, however, lost his job. While probably every risk-assessing official in Europe watched the events of the case very narrowly, in the European public, it attracted comparatively little attention.

The E. coli bacteria crisis in 2011, by contrast, put Europe on red alert. After the bacteria had claimed one person’s life, the German authorities and the European Commission set into motion all available emergency mechanisms. In this course, Germany publicly warned, i.a., against Spanish cucumbers, which it falsely supposed to be contaminated with the bacteria. The damage of the warning was immense, as already within the first two weeks farmers in the fruit and vegetable sector lost more than

¹ Hereinafter referred to as EU.

² Hereinafter referred to as *AGM-COS.MET*.

812 Mio. €. Two weeks later, sprouts in Saxony (Germany) could be identified as the actual source of the outbreak; their contaminated seeds had already been imported from Egypt into Germany in 2008. During the entire crisis, throughout Germany, 3842 persons became infected with the bacteria; 53 patients died.

To verify its hypotheses, the present study examines the in both cases applicable secondary legislation—the Foodcode,³ respectively the Machinery Directive (MD)⁴ and the General Product Safety Directive (GPSD)⁵—and thereby seeks to reveal its market-friendly architecture. For the case of the vehicle lifts, it will furthermore debate the reactions of Finland—represented by the assessing official Mr. Lehtinen and his superior Mr. Hurmalainen—and look at the ECJ judgement related thereto. In respect of the E. coli bacteria crisis, it will ventilate the behaviour of Germany, the European Commission, and the various other European bodies and Member States, which all seemed to be torn between socio-political and market interests. For both cases, the thesis will further go into the question whether the bodies simply failed to assess the risks properly, whether non-product related factors motivated them (e.g. the occurrence of a death), or whether the bodies pursued the same goal—the protection of the internal market—, but the individual characteristics of the products forced them to use partially deviating approaches. The intention of this thesis is to argue that mainly the latter was the case—namely, that being foodstuff, for product-related reasons (cultural, sociological and factual ones), the contaminated vegetables had from the beginning huge potential to become emergencies—, and to shed light on the reasons therefor.

The first case illustrates very clearly the claimed strong tendency towards the establishment and the protection of the European single market, against which the protection of consumers has to take second place. Although the vehicle lift posed a potentially deadly risk to persons, both on Member State as well as on EU level, the market interests prevailed. Firstly, in order to protect the market from trade barriers, the Finnish Ministry vehemently opposed any action of Mr. Lehtinen aiming at the withdrawal of the vehicle lifts from the market. Secondly, the provisions of the Machinery Directive admittedly empowered the affected Member State, Finland, to initiate a safeguard procedure, however, precluded any other (European) body from taking actions. More precisely, according to the

³ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ No L 31 [hereinafter referred to as Foodcode].

⁴ Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery, OJ L 207, 23.7.1998 [hereinafter referred to as old MD]; replaced by Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) OJ No L 157, 9 June 2006 [hereinafter referred to as MD].

⁵ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety, 15 January 2002, OJ No L 11 [hereinafter referred to as GPSD].

Machinery Directive, Member State failure in whatever form can only be fought within the specific procedures. This was also confirmed by the ECJ. When being consulted in context of the civil law case against Finland and the official, it judged that the MD formed the statutory framework for any action, meaning that beyond its provisions, no concerns such as health protection aspects could be cited. Yet, faced with the task of reconciling the two goals, the MD legislator firstly, implemented only as many safety instruments as would be beneficial to the internal market and secondly, formalised the procedure for machinery in such a way that outside the same, there is no room for claiming health concerns. As will be shown, the prioritization of market interests also coincides with the alignment in the Treaties.

At first glance, *AGM-COS.MET* seems to stand in marked contrast to the *E. coli* bacteria crisis, in which the German authorities, issuing various public warnings, adopted a rather protective approach. However, also here, the reactions resulted from the idea to protect the European market.

In Germany, all types of *E. coli* bacteria are notifiable as part of the usual monitoring procedures, see 7.1 (1) 13.a IfSG.⁶ It therefore is to be believed that, from the occurrence of the first (verified) cases on 08 May 2011 on, the health service received corresponding reports. Nevertheless, only on 22 May 2011, more than 200 cases of infection⁷ and one dead person later,⁸ the German health services as well as the Commission launched their alert systems and increased the investigation efforts. Three days later, the authorities issued their first public warning.

Measured against the intensity of the outbreak, it is remarkable that it took the authorities two entire weeks⁹ before they finally made use of the (confidential) notification mechanisms—apparently only then, in their view, the threshold for taking action was exceeded. Two food-risk-related aspects played a decisive role here: firstly, that the potentially deadly *E. coli* bacteria *evidentially* spread *uncontrolled* all over Northern Germany, and secondly, that the *little social acceptance* of food risks continuously increased the political pressure. Shortly afterwards, empirical data motivated the German authorities to issue a first general warning against various vegetables from Northern Germany; the data confirmed, i.a., that 88 % of the persons affected had consumed cucumbers. However, they only ‘limited’ their warning to Spanish cucumbers, when the authorities believed to rely on verified scientific findings confirming that cucumbers imported from Spain were contaminated with the disease-causing serotype of *E. coli* bacteria. Soon later, it turned out that their scientific findings had been wrong and that only the empirical data remained to consolidate their suspicion; at this time,

⁶ The German Protection against Infection Act: Infektionsschutzgesetz (IfSG), 20 July 2000, BGBl. I p. 1045.

⁷ Technical Report 30 June 2011, p. 7.

⁸ Aggressive EHEC-Form sorgt für Todesfälle 2011.

⁹ Already before, the number of infections had increased massively: 13 May 2011—more than 50 cases, 16 May 2011—more than 100 cases, 19 May 2011—more than 150 cases (Technical Report 30 June 2011, p. 7).

however, they had already pronounced the warning against cucumbers from Spain. From that point on, the public as well as the other European bodies piled on the already strong pressure. Without the wrong warning, the search for the (actual) source would probably have been much less feverish and panic.

The day the German RKI informed the public about the outbreak (25 May 2011)—three days after the notification—, the European Commission convened the first audio-conference. At this point, the crisis had already crossed the German borders (15 cases in Sweden) and started to take distorting effect on the internal market. Aiming to restrict the disadvantages for the internal market to a minimum, in the following conferences, the European bodies sought to accelerate the proceedings considerably and finally insisted on sending European experts to the location of the outbreak. In particular, they repeatedly called the adopted measures into question and criticized them for being taken too hasty. The attitude of the Commission and the Member States shows that, despite the precautionary principle, in their view, a mere suspicion even if based on empirical data can barely justify the release of a warning.

The case thereby reflects the main conflict in the regulation of food risks: the regulators are pressurized on the one hand, to restrict the free market as little as possible, and on the other hand, to adopt measures that most widely prevent the market from the economically very harmful food-borne risks.

1. Research question and methodology

a. Hypotheses

By an analysis of the cases and the respectively applicable (sector-specific) legislation, this thesis seeks to examine the following hypotheses:

1. On EU level, the protection of the health and well-being of consumers mainly serves as a mean for the establishment of the internal market; the interests of the internal market limit the level of health protection.
2. In contrast to non-foodstuff risk, foodstuff risks are usually treated as emergencies.

b. Methodology

In spite of pre-eminently being a practical profession, legal research often lacks practical approaches. For an analysis of tendencies that are mainly perceptible in practice, however, the study of cases from practice seems to be unavoidable.

The tendencies to be explored in the present research are the systematic postponement of health considerations and the different handling of risks depending on whether they originate from food or from non-food consumption goods. Whereas, therefore, the first example is taken from product safety regulation (non-food), the second one originates from foodstuff regulation. Both cases confronted their actors with critical situations for human health. Despite their seriousness, however, they allowed internal market considerations to take large effect—even though to varying degrees. Based on the analysis of both, this thesis aims to draw a conclusion about the way the risk management was organised in the two cases and to explore the differences. What weight was given to the health and well-being protection? What distinguishes food from machinery and how does this affect the regulatory approach?

Indeed, it is understood that one isolated case is not necessarily representative of an entire field; for a start, the two cases therefore must be regarded as independent of other European cases. Nonetheless, on some points, they do allow to draw general conclusions—that is to say, on the shape of the risk regimes in the two fields as well as on the behaviour pattern of assessing officials. On the one hand, the present case study is based on an analysis of abstract legal bases, which constitute the general pattern for the implementation in practice. On the other hand, especially the European risk regulation is the result of a rich and informed case-law developed by EU courts.¹⁰ Hence, the proceedings in each individual case are not only of great importance for the single situation but also for future practice;

¹⁰ See, e.g., Alemanno, JMWP 18/08, p. 2; Vos, JCP 2000; Fioritto & Simoncini, p. 120; Ely et al. 2009, p. 34.

they gradually shape the risk regulation. On top of that, since they bear the personal as well as the liability risk, when assessing, the officials naturally take into account any practice (allegedly) emerging from court judgments and Member State actions.¹¹ Consequently, their behaviour inevitably reflects previous case practice or at least the officials' fears arising from the latter.¹²

c. Structure

After having *reviewed the literature* in the field (2.), in its third part, the thesis analyses and compares the two cases from practice (3.). By checking them against each other as well as against their legal bases, it aims to reveal differences arising from the respective secondary legislation and the risk-posing products. For that purpose, it first surveys the proceedings in both cases (3a.), the applicable secondary legislation (3b.) and the functions undertaken by the various bodies involved (3c.). In the next step, it investigates the respective secondary legislation by exploring the addressees (3d.), the scope (3e.), the allocation of the burden of proof (3f.), the implementation of obligations as regards the risk analysis and the adoption of measures (3g-i), and finally the legal implementation of 'emergencies' (3j).

The fourth part of the thesis considers possible *reasons* for the differences in the treatment of both cases that go beyond the secondary legislation (4.). For this purpose, part four addresses the interdependence of *safety and trade* (4a.) and provides an overview of the *health and well-being protection in EU primary law* (4b.). Subsequently, it concerns the *predisposition of food risks* to be treated as emergencies (4c.). The part therefore surveys the interdependence of public health and market interests. Although too many product safety requirements lead to trade barriers, a certain level of health protection constitutes one aspect of a functioning European single market, as consumers need to trust in the harmlessness of a product. Public health thus serves as a mean for the internal market. This idea is also reflected in EU primary law and becomes particularly apparent when comparing the respective Treaty competences. Food risks, however, present a special challenge to the internal market. Due to their individual characteristics, against food risks, the protection of the internal market usually requires much more effort than against other risks.

In the fifth and last part, on base of its findings, the thesis eventually *revises its hypotheses* (5.).

¹¹ See, e.g., Micklitz/Roethe, European Product Safety Legislation 2007.

¹² Ibid., p. 104, described as 'individuated fear.' Indeed, fears such as of failing to manage a risk pose risks themselves, see Hutter 2010. See also Viens 2011, who addresses the issue of 'normative uncertainty,' see Viens 2011, p. 137.

2. Literature review

Although there do exist several studies exploring the economic, political and sociological aspects of regulation,¹³ only a few canvass the competing values attached to the assessment of risks (in emergencies).¹⁴ Thus, researchers have addressed the necessity in product safety to balance health and well-being considerations with economic interests, yet, mostly without carefully analysing the interaction of both objectives—that is to say, both the negative and the positive correlation—, without looking at their implementation in law, and without paying attention to the risk-posing product.¹⁵

a. Internal market vs. health protection

It is widely acknowledged that market interests limit health protection efforts.¹⁶ Armstrong and Butler (1998), for instance, point out that at the heart of any discussion of technical harmonisation lies the need to reconcile the demands of the free movement of goods with the need to ensure valued regulatory objectives, such as the protection of public safety or consumer and environmental protection.¹⁷ Balancing safety against costs therefore is a traditional public policy function (Brannigan 2011),¹⁸ for which the regulator evaluates potential losses against potential benefits (Jachia and Nikonov 2011).¹⁹ Fioritto and Simoncini (2011) even go so far to consider every zero-risk approach as “unacceptable for Western democracies,” because it would “quash fundamental rights in an irreversible way.”²⁰ Talking of tolerable risks, they argue that the regulatory framework should engage in the process of mitigation only as long as the costs do not exceed the benefits, in order to provide a due level of protection only against those threats whose materialization would produce intolerable effects for the affected community.²¹ In their view, standards therefore are a sound compromise between the necessity to ensure due protection against disastrous risks and their low probability of occurrence.²²

Others lay great stress on the function of consumer safety as a positive mean for the market. Thus, Shuibhne (2006) classifies consumer protection rather as a market than a non-market concern,

¹³ See, e.g., Ogus 1994; Baldwin 1995; Baldwin et. al 1998; Hancher 1990; Abraham & Lewis 2000.

¹⁴ See, e.g. Hodges 2005, p. 7.

¹⁵ An exemption are, e.g., Micklitz and Roethe (1994), who suggest that the various steps in the management of emergencies are largely guided by the different product categories, pp. 51/52.

¹⁶ See, e.g., Hodges 2005, p. 8; Brannigan 2011, p. 105; Fioritto & Simoncini 2011, p. 118; see also Wilke et al. 2012, who seek to work out a conceptual framework for economic assessment of the effectiveness of preventive measures for food safety improvement.

¹⁷ Armstrong & Butler 1998, p. 145.

¹⁸ Brannigan 2011, p. 105.

¹⁹ Jachia & Nikonov 2011, p. 152.

²⁰ Fioritto & Simoncini 2011, p. 130.

²¹ Ibid., pp. 118/119.

²² Ibid., p. 130.

because it relates more to the demand than to the supply side.²³ According to St. Clair Bradley (1999), a wide variety of measures may be adopted in pursuit of the proper functioning of the internal market, such as the horizontal harmonization of safety requirements for consumer products.²⁴ Likewise, Zurek (2012) recognizes the interdependence of the market on the one hand, and social needs on the other. According to her, the regulation of the market is embedded in a certain society, in a way that both are interrelated and cannot function properly when being disconnected;²⁵ paradoxically, however, according to her, various elements of the current European regulatory system are contrary to the declared goals of the Social Europe model.²⁶ Hodges (2005) finally deals with the limited significance of health protection in law; he determines that the basis upon which the Community possessed competence to legislate in relation to product regulation is based almost exclusively not upon a policy of consumer protection or the achievement of a level of safety but upon the facilitation of trade.²⁷

b. What makes an ‘emergency?’

(1) The EU legal acts relevant for food and machinery barely regulate ‘emergencies.’ Neither the GPSD nor the MD mention them; only the Foodcode implements respective competences. Yet, even in the latter, there is no legal definition and no obligation to act. Clearly, in emergencies, the regulation relaxes its strict requirements for an intervention; nevertheless, it leaves the reader in the dark about what to understand under the term ‘emergency’ and about the dispensable requirements compared to the normal state of affairs. It seems to be clear, however, that emergency risks are serious.

(2) Likewise, in the legal research, precise definitions are rare and relinquish to explore predispositions of certain types of risk-posing products, such as of foodstuffs. For instance, according to Sorell (2002), “an emergency is a situation, often unforeseen, in which there is risk of great harm or loss and a need to act immediately or decisively if the loss or harm is to be averted or minimised.”²⁸ Another definition may be found in a sub-clause of Micklitz and Roethe (1994), according to which all those risks come under the category of emergencies that require speedy action on behalf of the authorities.²⁹ However, later on, they remark that neither the legislator nor those who apply the law can tell in advance what an emergency is.³⁰ According to Micklitz and Roethe, the identification of a case as an ‘emergency’ is

²³ Shuibhne 2006, p. 63.

²⁴ St. Clair Bradley 1999, p. 99.

²⁵ Zurek, YPES 2008, pp. 48/49.

²⁶ See Zurek 2012, p. 25.

²⁷ Hodges 2005, p. 27.

²⁸ Sorell, PoAS 2002, p. 22.

²⁹ Micklitz & Roethe 1994, p. 70.

³⁰ Micklitz & Roethe 1994, p. 70.

the result of complex social procedure in which the parties involved weigh and measure ‘risks’, ‘dangers’ and ‘damage,’ in order to be able to decide whether it is an ‘emergency.’³¹

Although scholars seem to have agreed upon some core properties, mostly, they paraphrase or describe emergencies by using abstract terms or by adducing individual characteristics; thus, they often refer to ‘crises,’ ‘catastrophic risks’ or ‘disasters,’ or else, point out the high level of uncertainty or the sudden occurrence. Fioritto and Simoncini (2011), for instance, identify that by resorting to the category of emergency one achieves protection against *catastrophic risks*;³² the instruments of emergency is employed in the face of their *unforeseeable and sudden occurrence*.³³ Brannigan (2011) illustrates that in *crises situations*, the *lack of suitable scientific evidence* about the hazard is a normal problem.³⁴ Alemanno (2011) finally distinguishes between mitigation and emergency response; in his understanding, the former attempts to reduce the potential impact of a *disaster* before it strikes, while the latter, by contrast, tends to do so *after the event*.³⁵

The regulation of emergencies needs to be effective and both to exert and to withstand political pressure. Thus, according to Brannigan (2011), in an emergency environment of high uncertainty, there is a great deal of room for political pressure to affect the outcome, especially by shifting the burden of proof.³⁶ According to Micklitz and Roethe (1994), the intensity of emergency risks requires professionalization of the management; therefore, they plea for a concentration of product safety policy on emergencies and a downgrading of routine inspections to some form of pre-procedure preparing the selection and elimination of all those risks which do not come under the category of the former.³⁷ Fioritto and Simoncini (2011) take the view that in case of catastrophes, cost-benefit analysis cannot be the only methodology used to assess the significance of the risk, since the tolerability does not overlap with a mere mathematical or statistical analysis of probability but is a regulatory concept that related to the effectiveness of the regulation.³⁸ To achieve efficiency in legal systems, Dyzenhaus (2011) even argues that emergency regulation cannot be limited by the rule of law.³⁹ Sorell (2002) furthermore describes emergencies as occasions for serious rupture of moral conventions, which can undermine everyday morality itself at a place and time.⁴⁰ More precisely, according to

³¹ Micklitz & Roethe 1994, p. 63.

³² Fioritto & Simoncini 2011, p. 118.

³³ Fioritto & Simoncini 2011, p. 119; see also Briggs 2011, pp. 166/167.

³⁴ Brannigan 2011, p. 102.

³⁵ Alemanno 2011, xxii; see also Fioritto & Simoncini 2011, p. 115, who emphasise that risk regulation would offer protection beforehand, and emergency regulation generally would apply *in the aftermath*.

³⁶ Brannigan 2011, p. 102.

³⁷ Micklitz & Roethe 1994, p. 70.

³⁸ Fioritto & Simoncini 2011, p. 119.

³⁹ Dyzenhaus 2001, pp. 21/22. In 1922, Schmitt even argued that an effective response to an emergency must be outside the rule of law, as regulators would fail to anticipate novel crisis; no legal order could reasonably foresee all potential crisis, Schmitt (1922).

⁴⁰ Sorell, PoAS 2002, pp. 31/32.

Viens (2011), in emergencies, the features of a situation change significantly and can produce a corresponding change to the balance of normative reasons—i.e. compared to balance of reasons in normal circumstances.⁴¹ Likewise, Brannigan (2011) states that in a crisis environment, principles can disappear under the weight of economic and political considerations.⁴²

(3) This thesis defines emergencies as all situations of evident risks that due to potentially widespread and severe consequences for human health and/or well-being (for food risks)⁴³ require rapid intervention. Evidence is given in all cases where damage has occurred already or, considerably more seldom, where the occurrence is imminent.⁴⁴

In most cases, before a risk may be qualified as emergency, severe damage, such as a fatality, has to occur, as precisely such damage proves the severity. Assured knowledge alone, by contrast, usually merely leads to an application of the rules for the normal state of affairs, e.g. to a regular recall of the risk-posing product. In respect of a certain source, on the other hand, evidence is dispensable; quite the contrary, as the E. coli bacteria crisis has shown, unidentifiable cases of illness not only suffice to trigger emergency responses but even spur them, as these cases visualize the imminent loss of control: bacteria spread fast and uncontrolled, while opportunities to contain them continuously shrink.

In fact, emergencies regularly require rapid intervention precisely because of this imminent loss of control. Additionally, however, this prerequisite clarifies that not every risk with potentially widespread and severe consequences requires rapid intervention; instead, there are also socially accepted risks, e.g. the usage of cars.

c. Peculiarities of food risks – the significance of the risk-posing product

Some risks are particularly difficult to regulate i.e. those that we cannot control by our actions, those that pertain to phenomena that we can only partially understand with our senses, and those that can result in fatal outcomes (Jachia and Nikonov 2011).⁴⁵ This holds true especially for foodstuff risks; however, only few studies are concerned with the particularities of the latter and even less with the consequences for the regulation thereof. Micklitz and Roethe (1994), however, acknowledge that there seems to be a major difference between foodstuffs and non-food products that is inherent to the product categories.⁴⁶

⁴¹ Viens 2011, p. 142. One feature of emergency was moreover ‘normative uncertainty,’ see p. 137.

⁴² Brannigan 2011, p. 102.

⁴³ To mind comes here for example the meat adulteration scandal in 2013, which did not pose any risk to health, but affected the well-being by arousing disgust, see, e.g., European Commission on Horse Meat 2014.

⁴⁴ One example of such imminent damage is the volcanic ash crisis in 2010, see, e.g., Governing Disasters 2011 by A. Alemanno (ed.).

⁴⁵ Jachia & Nikonov 2011, p. 152.

⁴⁶ Micklitz & Roethe 1994, pp. 67/68.

Foodstuff risks differ from non-foodstuff risks in many respects. First, unlike other consumption goods, food is of fundamental importance to life.⁴⁷ Poor food safety therefore can have devastating effect. This particularly applies to areas of the world where food is a scarce commodity; yet, due to the particularities of foodstuff, also areas disposing of large quantities of food are faced with dangers.

Firstly, toxic or contaminated foodstuffs extensively spread in all directions. Kapur and Smith (2011) argue that the modern global ‘food chain’ is much more like a matrix than a chain, especially when considering processed foods with multiple ingredients.⁴⁸ As Jannssen and Voragen (1997) demonstrate, for socio-economic reasons, precisely such manufactured foods are what the majority for its daily food supply depends on—only very few people, by contrast, forego industrially processed food and seek to go back to nature.⁴⁹ In fact, the food industry is the single largest manufacturing sector in the EU in terms of turnover, added value and employment, and its share in the sector continues to grow.⁵⁰ Likewise non-food consumption goods pass through many working steps (such as the complex machinery of cars), each of which provides great scope for new risks to occur, e.g. because of the (improper) incorporation of (further) risk-posing components. The particularities of foodstuffs, however, considerably increase their predisposition for the occurrence of risks.

De Vries (1997) distinguishes health risks associated with food intake roughly into two types: toxicological ones⁵¹ and microbiological ones (which again have to be subdivided in risks of infection and risks of intoxication).⁵² At least the latter are peculiar for foodstuff consumption goods. De Vries stresses that during the production, processing and packaging, foodstuffs are firstly exposed to contaminants (particularly when being processed in a raw state) and secondly, subject to (bio)chemical changes.⁵³ Hence, not only the contaminated ingredients themselves scatter through the ‘food matrix;’ instead, with every processing step, they also possibly pass their biological agents on other (harmless) products. There, in a minimum of time, they increase a thousand-fold. This is precisely why, as Kapur and Smith (2011) reveal, biological agents have been the basis for some of the most terrifying threats to human well-being in recorded history, such as leprosy, black plague, smallpox, anthrax, Ebola or SARS (severe acute respiratory syndrome).⁵⁴ Apart from that, as de Vries states, during the processing, (bio)chemical changes take place that form potentially hazardous compounds, e.g. due to the use of additives, of preservatives, of biotechnological developments (e.g. of gene manipulation) as well as

⁴⁷ Jannssen & Voragen 1997, pp. 3 f.

⁴⁸ Kapur & Smith 2011, pp. 320f.

⁴⁹ Jannssen & Voragen 1997, p. 3.

⁵⁰ Zurek 2012, p. 5.

⁵¹ See, e.g., Jannssen, Put & Nout 1997, pp. 8ff.

⁵² De Vries 1997, Preface; see also Jannssen, Put & Nout 1997, p. 20 or Notermans & Mead (1999), pp. 409ff.

⁵³ De Vries 1997, Preface; see also Jannssen & Voragen 1997, pp. 5/6.

⁵⁴ Kapur & Smith 2011, pp. 306f.

due to chemical deterioration.⁵⁵ For that reason, as Micklitz and Roethe (1994) expound, routine inspections often do not suffice to discover unsafe foodstuffs;⁵⁶ instead, the food inspectors have to rely on their experience and autonomy and to make samples even in cases where a systematic evaluation of the risks in the laboratories has taken place, but does not show the presumed results.

Non-food consumption goods, by contrast, either suffer from toxicological or from technical risks, such as product defects or malfunctions; both however, unlike pathogens, neither multiply nor encroach.⁵⁷ The toxicological substances such as plasticisers are not ‘contagious’ and thus do not spread so quickly or uncontrollably. Often, they moreover damage consumers only in a long-term perspective when being used over a longer period or in an ‘inappropriate’ manner, e.g. when children (repeatedly) put toys in their mouth (like food). Compounds in foodstuff, by contrast, develop their dangerousness precisely when being used as intended, namely when being ingested.

A further issue is the traceability of food risks. Whereas damages caused by non-food risks regularly can be assigned to their sources, due to the quick and extensive spread, food risks often seem to be disconnected from their original source. Thus, starting from the outbreak, the authorities firstly need to locate the one contaminated food, e.g. meat of an infected animal, and secondly, as the circumstances may require, identify and locate any contaminated food plant the animal possibly consumed. Therefore, the search for the source of the outbreak can be complex, time-consuming and expensive. This is aggravated by the fact that food-borne diseases usually require an incubation time from 1 to 96 hours.⁵⁸ Even if being identified and located, the pathogens finally confront the risk regulators with the challenge to either isolate the products affected or to develop and prepare an antidote.⁵⁹

Differences between food and non-food consumption goods moreover come to bear in the structures of risk assessment. Thus, according to Micklitz and Roethe (1994), in the processing of non-food risks,⁶⁰ expert knowledge is the dominating factor; the processing resembles a closed system where access is limited to those who belong to the guild of experts.⁶¹ They identify “a structural preponderance of experts, the risk managers, in the evaluation *of - and* the decision making about [non-food] consumer goods.”⁶² Their analyse moreover reveals that in the processing of foodstuffs, by contrast, risk

⁵⁵ De Vries 1997, Preface.

⁵⁶ Micklitz & Roethe 1994, p. 68.

⁵⁷ Exceptions, e.g., are radiating substances.

⁵⁸ Jannssen, Put & Nout 1997, p. 20.

⁵⁹ Even the preparation of biological agents for mass dispersal (as a weapon) requires sophisticated laboratory and production facilities, see Kapur & Smith 2011, p. 305.

⁶⁰ Micklitz & Roethe 1994, p. 51: (1.) notification, (2.) processing, (3.) evaluation and decision, (4.) warning the public at large.

⁶¹ Micklitz & Roethe 1994, pp. 51/52.

⁶² Micklitz & Roethe 1994, p. 52.

managers and decision-makers have to be brought together, meaning that the different levels of competences have to be combined. The preponderance lays with the political decision-makers; foodstuff test results gain societal importance only if the latter interpret them as a source of action.⁶³

In today's society, it is increasingly important how the public perceives risks;⁶⁴ it decisively influences the political attitude. According to Micklitz and Roethe (1994), in case of technical consumer goods, the users often are able to discover the existence of a danger themselves; whether or not the goods constitutes an emergency is subject to everyday life experience.⁶⁵ Whether or not a foodstuff is dangerous, by contrast, is subject to complicated chemical testing procedures; the users feel ill after having eaten unsafe food, but they seldom know where their ill-feeling is coming from; sometimes not even the professionals involved know what they should search for.⁶⁶ As de Vries (1997) reveals, the perception of food-related hazards usually does not agree with the acknowledged health risks assessed on base of accepted scientific criteria. As an example, he alleges pesticide residues, whose effects concern the public, although, in fact, the risks resulting thereof are minimal.⁶⁷ Referring to epidemiological data and to a survey held in the Netherlands in 1990, also Jannssen, Put and Nout (1997) illustrate that as a matter of principle, the perception of food hazards by consumers and their actual importance differ widely.⁶⁸ One reason for this might be the feeling of disgust, which plays a decisive role in the perception of food.⁶⁹ The legislator has recognised the significance of the latter and therefore laid down that food shall not only be deemed to be unsafe if it is considered to be injurious to health, but also if it is simply "unfit for human consumption," Art. 14.2 Foodcode. In the eyes of the public, it seems to make a huge difference whether 'body-internal' or 'body-external' factors potentially harm the well-being, i.e. whether a disease or a car accident causes damage.

The predisposition of foodstuffs to be subject of risks finally heightens the likelihood of biological terror campaigns⁷⁰ and thus the emergency preparedness. In fact, the U.S. believes biological terror campaigns to be one of the most dangerous weapons of mass destruction.⁷¹ As Martin, Christopher

⁶³ Micklitz & Roethe 1994, pp. 51/52.

⁶⁴ De Vries 1997, Preface.

⁶⁵ Micklitz & Roethe 1994, p. 67.

⁶⁶ Micklitz & Roethe 1994, p. 67.

⁶⁷ De Vries 1997, Preface.

⁶⁸ Jannssen, Put & Nout 1997, p. 20: microbial contamination: 22 % in the perception vs. 49.9 % of the actual importance; nutritional imbalance: 0 % vs. 49.9 %; environment contaminants: 31 % vs. 0.05 %, toxins: 10 % vs. 0.05; food additives 30 % vs. 0.0005 %; others, e.g. packaging materials: 7 % vs. 0 %.

⁶⁹ See, e.g., so-called Birkel-Case, Decision by the OLG Stuttgart (Higher Regional Court) of 21 March 1990, 1 U 132/89, NJW 1990, 2690, which addressed the mistakable depiction of the use of disgusting liquid eggs during the production of pasta.

⁷⁰ See Kapur & Smith 2011, pp. 305ff.

⁷¹ Are we prepared? Four WMD crises that could transform U.S. security 2009, pp. 71ff.

and Eitzen (2007) emphasize, already during the Peloponnesian War, biological agents were used as agents of warfare.⁷²

The present study does not only aim to elaborate systematic particularities that arrive from various risk-posing products—more precisely, the predisposition of foodstuff risks to become an emergency—, but also compares two different regulation regimes by using a case- and thus practice-driven approach. By doing so, this research seeks to call attention firstly, to the great importance of the internal market and secondly, to the conscious or unconscious diversities in the effective treatment of risks, as the awareness of these phenomena seems to be essential condition for appropriate law- and decision-making.

⁷² Martin, Christopher & Eitzen 2007, pp. 1ff.

3. Substance: The two cases and their legal bases

a. Summary of the proceedings in the two cases⁷³

i. ECJ Case C-470/03: *A.G.M.-COS.MET Sri v Suomen valito/Tanno Lehtinen*,⁷⁴

The Italian company A.G.M. produced and sold various types of vehicle lifts with similar constructions, which then were imported to Finland by the Finnish company Pörhöön Tuontiliike. In 1997, an authorised Italian company certified the type AGM G 35 of the vehicle lifts as complying with the old Machinery Directive⁷⁵ and the lifts were granted the CE marking.⁷⁶

On 11 May 2000, the Ministry of Social Affairs and Health in Finland received a market supervision report issued by the Vaasa health and safety district office⁷⁷ that, with regard to type AGM G 35 T/E, deficiencies had been detected, in particular firstly, a bending of the front lifting arms and secondly, a weak locking of the lifts. For that reason, the report advised the Ministry to restrict or even prohibit the sale and use of the vehicle lifts.⁷⁸ A report drafted by Mr. Lehtinen, chief engineer and official of the Ministry of Social Affairs and Health, shared this assessment. In response, A.G.M. proposed a new locking system; when loaded at the maximum and driven onto the least favourable direction, however, the vehicle lift still showed defects.

With the knowledge of the Ministry, on 17 January 2001, Mr. Lehtinen was interviewed by a national television channel. Upon inquiry of the presenter, he stated that the vehicle lifts presented an immediate danger for the workers beneath the load; the certification body therefore had misinterpreted the provisions. Mainly because Mr. Lehtinen had opposed the Ministerial instructions by expressing a point of view differing from the official position, his superior Mr. Hurmalainen removed him from dealing with the case. Despite of several supporting reports, i.a., by the Metalworkers' Union,⁷⁹ in October, Mr. Lehtinen eventually received a written warning under the Law on State

⁷³ For a detailed prescription of the proceedings, see Annex I.

⁷⁴ Case C-470/03, Judgment of the Court of 17 April 2007, *AGM-COS.MET v Suomen valito/Tanno Lehtinen* [2007] E.C.R. I-2749. The summary is based on the judgment.

⁷⁵ Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery, OJ L 207, 23.7.1998 [hereinafter referred to as old MD]; replaced by Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) OJ No L 157, 9 June 2006 [hereinafter referred to as MD].

⁷⁶ See Opinion of Advocate General Kokott in *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03) [2007] E.C.R. I-02749, para. 26.

⁷⁷ According to the German translation of the judgement, a Finnish authority responsible for the protection of workers, see *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03), para. 21.

⁷⁸ See Opinion of Advocate General Kokott in *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03), para. 29.

⁷⁹ *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03), para. 32.

officials for breaching his obligations as an official by continuing to give a misleading picture, even after the case had been withdrawn from him on 16 February 2001.

When the company A.G.M. finally claimed compensation from the Finnish State as well as from Mr. Lehtinen for the damage caused to its business,⁸⁰ the Tampere District Court referred to the Court of Justice a number of questions on interpretation of the rules on the free movement of goods and on the conditions of liability for infringement of Community law. In particular, it raised the question whether Mr. Lehtinen's conduct as a measure having equivalent effect to quantitative restrictions had transgressed the free movement of goods.

The Court of Justice found that Mr. Lehtinen's conduct had violated Art. 4.1 old MD. Opinions expressed by an official could be attributed to the Member State itself, if their form and circumstances gave the persons to whom they were addressed the reasonable impression that they were pronouncements of the State, taken with the authority of the official's office, and not his personal opinions.⁸¹ This applied to Mr. Lehtinen's utterances, so that they could be assigned to the Finnish State. As regards the breach of the free movement of goods, referring to Art. 4.1 old MD (Art. 6.1 MD), the Court declared that if, as in the present case, a matter was subject of exhaustive harmonisation at Community level, the latter was the benchmark, not primary law, such as Art. 34 AEUV (ex-Art. 28 EC); hence, the proceedings in the present case had to be assessed on base of the MD. Because of the CE marking, Article 5.1 old MD (Art. 7.1 MD) presumed the compliance of the vehicle lifts. Despite this presumption, indeed, the Member States were obliged to adopt appropriate measures to withdraw machinery from the market, if they ascertained that the latter posed a danger, see Art. 7.1 (Art. 11.1 MD). In the case of the vehicle lifts, however, the competent authorities had not ascertained any risk nor taken measures to withdraw the machines. The conformity thus had to be presumed and possible obstacles for the internal market to be removed.

The Court moreover dismissed any justification for the statements in question both on grounds of freedom of expression and of health protection. The freedom of expression (Art. 10 ECHR) of officials could not be plead by the Member States to justify obstacles to the free movement, as they so evaded their liability.⁸² The consideration of health protecting aspects was conclusively regulated in the Directive, in particular in Art. 7.1 old MD.⁸³

In the end, the parties settled the case in the Tampere District Court.

⁸⁰ According to A.G.M., the collapse in profit alone was about 300 000 € in 2001 and about 750 000 € in 2002, see Opinion of Advocate General Kokott in *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03), para. 45.

⁸¹ *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03), para. 57.

⁸² *Ibid.*, para 72.

⁸³ *Ibid.*, para 68.

ii. The E. coli bacteria crisis in 2011

In the E. coli bacteria crisis in 2011, the German authorities publicly warned, i.a., against Spanish cucumbers, which they falsely supposed to be contaminated with E. coli bacteria serotype O104:H4. The financial damage of the warnings was immense.⁸⁴ Almost from the very beginning, farmers, media and governments criticised the German authorities for a lack of coordination and accused them to issue wrong warnings prematurely, while the government only stood on the sidelines.⁸⁵

In winter 2008/09, a company in Lower Saxony (Germany) had imported fenugreek seeds from Egypt to Germany for its sprout production, without knowing, however, that the seeds were contaminated with *Shiga Toxin-producing Escherichia coli* (STEC) bacteria, serotype O104:H4.⁸⁶ From 8 May 2011 on, several cases of STEC-infected human beings occurred in Northern Germany. The ill people complained about initially watery and later bloody diarrhoea, abdominal pain, nausea, vomiting and in some cases about fever. The outbreak reached its peak on 22 May 2011 and ended on 25 July 2011.⁸⁷ During this period, throughout Germany, 3842 cases of infected persons were reported to the Robert Koch Institute (RKI); 855 cases were affected with the hemolytic-uremic syndrome (HUS), a severe complication of E. coli disease, which is characterized by kidney failure, impaired blood clotting and a destruction of the red blood cells; fifty-three patients died.⁸⁸

On the peak of the outbreak on 22 May 2011, the German health services as well as the Commission launched alert systems at local, national, EU and international level.⁸⁹ The German authorities sent a team of experts from the RKI to a restaurant in Hamburg to undertake further investigations and notified the EU of the ongoing outbreak by issuing a confidential EWRS report. To discuss the evolution of the outbreak and possible measures, the Commission convened daily meetings with the national public health and food safety authorities of the Member States and the relevant European risk assessment agencies, namely the European Food Safety Authority (EFSA), the European Centre for Disease Prevention and Control (ECDC), the European Reference Laboratory (EU-RL) for E. coli bacteria and the Directorate-General for Health and Consumers (DG SANCO).⁹⁰ In addition, the Health Security Committee (HSC) discussed possible responses to the outbreak.⁹¹

⁸⁴ According to the Coga-Cogeca working group, within the first two weeks of the crisis, the farmers in the fruit and vegetable sector lost more than 812 Mio. €, see Commission Staff Working Document Lessons learned 2011, with reference to an estimate made by the COPA-COGECA working group (two organisations representing European farmers).

⁸⁵ See, e.g., Kritik am Ehec-Krisenmanagement der Regierung 2011 or EHEC: Spanien beklagt Produktionsausfälle und prüft Schadenersatzanspruch 2011.

⁸⁶ EHEC-Ausbruch 2011.

⁸⁷ Technical Report 30 June 2011.

⁸⁸ Effective 16 August 2011, see EHEC/HUS-Ausbruch in Norddeutschland 2011.

⁸⁹ Commission Staff Working Document Lessons learned, 2011.

⁹⁰ Flash Report of the European Commission 2011.

⁹¹ See, e.g., Health Security Committee 2014.

Since the affected persons had consumed these vegetables increasingly, on 25 May 2011, the German RKI and the Public Health Authority Hamburg publicly warned against raw tomatoes, cucumbers and leaf salad from Northern Germany.⁹² Shortly afterwards, the RKI succeeded in identifying the specific serotype O104:H4.⁹³ On 26 May 2011, the ECDC declared that the source was still unknown, although cucumbers might be one source, as 88 % of the persons affected had consumed them.⁹⁴ Because the RKI had mistakenly declared cucumbers from Malaga and Almeria as tested positive on the particular serotype, Germany and the Commission finally issued general warnings concerning cucumbers from Spain in the RASFF portal.⁹⁵ The RKI corrected its statement in the conference on 30 May 2011 and on 01 June 2011, the Commission and Germany withdrew their alerts on cucumbers. Nonetheless, the RKI, the German Federal Institute for Risk Assessment and the Commission maintained their press releases on the websites warning against tomatoes, cucumbers and lettuce.⁹⁶

On 07 June 2011, due to a sample taken from a sprout producer in Lower Saxony, Germany issued a RASFF notification saying that an organic sprouts mixture from Germany was suspected to be contaminated with STEC bacteria.⁹⁷ In the audio-conference, the EU Laboratory for E. coli bacteria and Spain asked the German Federal Institute for Risk Assessment to share its methods used for the sampling of the sprouts.⁹⁸ The Commission, furthermore, requested the German representative to provide information about a press report saying that suspicious German meat was examined in the Czech Republic; since RASFF notifications ensured the traceability of products, it asked Germany to use the official channels. The next day, the German Federal Institute, the German Federal Office of Consumer Protection and Food Safety and the RKI publicly warned against the consumption of sprouts.⁹⁹ Only then, the German authorities withdrew their recommendation to avoid the consumption of raw tomatoes, cucumbers and leaf lettuce. On 25 June 2011, France issued a RASFF notification saying that fenugreek seeds imported for sprouting from Egypt (packaged in the United Kingdom, via the Netherlands and via Germany) were suspected to have caused the outbreak.¹⁰⁰ The EFSA confirmed the source on 06 July 2011, whereupon the Commission temporarily banned sprout seeds from Egypt.¹⁰¹

⁹² Joint Opinion of the Federal Institute for Risk Assessment and the RKI of 25 May 2011.

⁹³ EHEC-Gurken - Spanien wehrt sich 2011.

⁹⁴ Audio-conference 26 May 2011.

⁹⁵ RASFF notification against Spanish cucumbers 2011.

⁹⁶ Neue epidemiologische Daten untermauern bisherige Verzehrsempfehlung des BfR 2011.

⁹⁷ RASFF notification against organic sprout mixture 2011.

⁹⁸ Audio-conference 07 June 2011.

⁹⁹ Technical Report 30 June 2011.

¹⁰⁰ RASFF notification against fenugreek seeds 2011.

¹⁰¹ Schutz vor EHEC 2011.

b. The character of the applicable secondary legislation

(1) For the most part,¹⁰² the risk management of the vehicle lifts followed the General Product Safety Directive (GPSD)¹⁰³ and the more specific Machinery Directive (MD).¹⁰⁴ The former regulates the product safety in general and thus is a gathering place. Depending on the sector, harmonising legislation partially imposes higher requirements, e.g. for toys or pharmaceuticals. For machinery, as in the case of the vehicle lifts, it is the MD that complements and supersedes the GPSD provisions.¹⁰⁵ Pursuing several goals—namely, the protection of consumers as well as of workers—, the MD occupies a special position.¹⁰⁶ The complex machinery often employed at workplaces puts particularly high safety requirements on the operator; for this reason, the provisions would probably be much less health-protective if the legislator had only considered the protection of consumers.

(2) The risk assessment in the *E. coli* bacteria crisis was based on the so-called Foodcode.¹⁰⁷ It lays down the general principles and requirements of food law and completely supersedes the GPSD. Being a Regulation, the Foodcode binds the Member States directly, without allowing them any time delay or deviations. The GPSD and the MD, by contrast, being Directives, have to be implemented into national law before coming into force¹⁰⁸ and therefore, not only allow the Member States a certain margin of time for the implementation but also confer on them some discretionary powers as regards the forms and methods to attain the Directives' objectives,¹⁰⁹ which weakens their legal force.

¹⁰² For non-food consumption goods, also other legal acts are relevant, such as Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L218/30, 13.08.2008, and Decision (EC) 768/2008 of European Parliament and Council of 9 July 2008 on common framework for the marketing of products, OJ L218/82, 13.08.2008. In the present case, however, due to the lack of space, they will not be included in the analysis. Due to its relevance in the *E. coli* bacteria crisis, the analysis will moreover be restricted to food and neglect feed products.

¹⁰³ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety, 15 January 2002, OJ No L 11 [hereinafter referred to as GPSD].

¹⁰⁴ Although in 2000, the old Machinery Directive had to be applied, in the following, I will refer to the provisions of the new Machinery Directive. Largely the relevant provisions are identical.

¹⁰⁵ About the MD as *lex specialis* in relation to GPSD see Art. 1.2 GPSD: "This Directive shall apply to all the products defined in Article 2(a). Each of its provisions shall apply in so far as there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned."

¹⁰⁶ See Recital (3) MD: "Member States are responsible for ensuring the health and safety on their territory of persons, in particular of workers and consumers and, where appropriate, of domestic animals and goods, notably in relation to the risks arising out of the use of machinery."

¹⁰⁷ For food consumption goods, aside from the Foodcode, also other legal acts are applicable, such as the Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139, 30.4.2004, p. 1 as corrected in OJ L 226 25.6.2004, and Directive 2003/99/EC (OJ L325, p31, 12/12/2003) of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC. In the present case, however, they were less important.

¹⁰⁸ However, after the expiry of the time-limit for implementation, also Directives may produce direct effect, see, e.g., Hartley 2007, p. 205.

¹⁰⁹ Hartley 2007, p. 205.

Although also the Foodcode demonstrates a tendency towards the abolition of trade barriers, compared to the GPSD and the MD, this is less evident.

(3) Both regulation regimes (of food and of non-food product safety) rely on compliance,¹¹⁰ which illustrates the large effects economic considerations take in product safety.¹¹¹ Requiring control of the safety of a product by the producer, before it is permitted to be placed on the market, is the central procedure that is both fundamental and common to safety mechanisms for all products.¹¹² Although official approval procedures unveil defects significantly more frequently and much faster, compared to the principle of compliance, they also occasion considerably more costs of labour as well as of materials¹¹³ and paralyse the market operations, in other words, they are much more expensive and thus affect the internal market to a far greater degree.¹¹⁴

Within the concept of compliance, only two events reveal weak spots: Either the authorities randomly uncover deficiencies upon spot-check inspections, or else, the risks posed by the deficiencies turn into damages, which attracts the authorities' attention.¹¹⁵ By relying on compliance, the legislator delegates large parts of the responsibility to the market participants, e.g. to the producer, the importer and/or the distributor.¹¹⁶ If these take the (precautionary) measures themselves, the authorities reduce the risk of being held liable for damages caused, e.g., because of the issuance of wrong warnings. Since the market participants are only to a limited extent interested in health protection however—usually only as long as this benefits their businesses—, they are still subject to official inspections.¹¹⁷ Apart from these inspections, only the occurrence of damages reveals risks.

Hence, with regard to the authorization to the market, both the Foodcode and the GPSD equally aid and abet the occurrence of damages. In principle, this also applies to the MD. Although before placing machinery on the market, the manufacturer must apply one of three procedures to assess the conformity (two of which involve third bodies that approve the compliance of the machinery), only within the full quality assurance procedure, each machinery is to be examined.¹¹⁸ For an EC type-examination, the notified body merely ascertains and certifies one representative model of

¹¹⁰ There are sector-specific exceptions, e.g. for pharmaceuticals.

¹¹¹ See, e.g., Hodges 2005, p. 8; Brannigan 2011, p. 105; Fioritto & Simoncini 2011, p. 118; Armstrong & Butler 1998, p. 145; Brannigan 2011, p. 105; Jachia & Nikonov 2011, p. 152; Fioritto & Simoncini 2011, p. 130.

¹¹² Hodges 2005, p. 87.

¹¹³ See Hodges 2005, pp. 110, 159, who argues in favour of a CE marking for all Community products.

¹¹⁴ Although, as will be shown, the internal market also benefits from a certain level of product safety.

¹¹⁵ Because of the intensity of emergency risks, Micklitz and Roethe (1994) plea for a concentration of product safety policy on emergencies and a downgrading of routine inspections, see Micklitz & Roethe 1994, p. 70.

¹¹⁶ With the CE marking, for instance, the manufacturer indicates that he takes responsibility for conformity of the product with the applicable requirements set out in Community harmonisation legislation, see Art. 1 (20) and Art. 30.3 Regulation (EC) No 765/2008.

¹¹⁷ On the Member State obligation to surveil and ensure that only safe products are placed, see, e.g., Art. 6.1 GPSD, Art. 4.1 MD, Art. 17.2 Foodcode.

¹¹⁸ See Annex X MD.

the machinery.¹¹⁹ The manufacturer therefore performs a comprehensive approval procedure only in very few cases.

c. Actors

The following part peruses the actions and tasks overtaken in the two risks assessments. It explores why during the E. coli bacteria crisis in 2011, the EU bodies became fully involved, while in the 2000/01 case of the vehicle lifts, there was no intervention at all.

i. The ECJ on the conclusiveness of the Machinery Directive

The lack of intervention in case of the vehicle lifts was mainly the result of the MD's conclusive character. As the ECJ clarified, there was and is no room to compensate Member State failure beyond the procedure provided by the Directive. If hence the affected Member State does not take action itself, there is no option for other European bodies to do so. Likewise, in the present case, there was no legal possibility for the Commission or the other Member States to intervene or to issue respective warnings via the Rapid Exchange of Information System (RAPEX).

When the company A.G.M. claimed compensation from the Finnish State as well as from Mr. Lehtinen for the damage caused to its business,¹²⁰ the Finnish Tampere District Court referred to the Court of Justice a number of questions on interpretation of the rules on the free movement of goods and on the conditions of liability for infringement of Community law. In particular, it raised the question whether Mr. Lehtinen's conduct as a measure having equivalent effect to quantitative restrictions had transgressed the free movement of goods. The Court of Justice found that Mr. Lehtinen's conduct had violated Art. 4.1 old MD, according to which Member States should not prohibit, restrict or impede the placing on the market and putting into service of machinery complying with the Directive. It ruled that the conduct could be assigned to the Finnish State, which therefore had not followed the procedure legally fixed in the Directive; in particular, due to the exhaustive harmonisation, Finland could not justify the utterances on grounds beyond the MD, such as health protection.

(1) Opinions expressed by an official could be attributed to the Member State itself, if their form and circumstances gave the persons to whom they were addressed the reasonable impression that they were pronouncements of the State, taken with the authority of the official's office, and not his personal opinions.¹²¹ This applied to Mr. Lehtinen's utterances. As regards the breach of the free movement of goods, referring to Art. 4.1 old MD (Art. 6.1 MD), the Court declared that if, as in the present case, a

¹¹⁹ See Annex IX MD.

¹²⁰ According to A.G.M., the collapse in profit alone was about 300 000 € in 2001 and about 750 000 € in 2002, see Opinion of Advocate General Kokott in *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03), para. 45.

¹²¹ *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03), para. 57.

matter was subject of exhaustive harmonisation at Community level, the latter was the benchmark, not primary law, such as Art. 34 AEUV (ex-Art. 28 EC); hence, the proceedings in the present case had to be assessed on base of the Machinery Directive. Because of the CE marking, Art. 5.1 old MD (Art. 7.1 MD) presumed the compliance of the vehicle lifts. Despite this presumption, indeed, the Member States were obliged to adopt appropriate measures to withdraw machinery from the market, if they ascertained that the latter posed a danger, see Art. 7.1 (Art. 11.1 MD). In case of the vehicle lifts, however, the competent authorities had not ascertained any risk nor taken measures to withdraw the machines. The conformity thus had to be presumed and possible obstacles for the internal market to be removed. In conclusion, the statement, which was attributable to the State and described certified machinery as contrary to the legal standard and dangerous, constituted a breach of Art. 4.1 old MD.

(2) The Court moreover dismissed any justification for the statements in question both on grounds of freedom of expression and of health protection. The freedom of expression (Art. 10 ECHR) of officials could not be plead by the Member States to justify obstacles to the free movement, as they so evaded their liability.¹²² The consideration of health protecting aspects was conclusively regulated in the Directive, in particular in Art. 7.1 old MD.¹²³

(3) The ECJ judgment mainly surprises because of its inconsistency. In its deliberations, the Court invokes Art. 6.1 MD, according to which the Directive conclusively regulates the Member State competences. On the one hand, Finland may be held liable for Mr. Lehtinen's utterances. On the other hand, examining whether Mr. Lehtinen was legitimated to warn, the Court *de facto* claims that due to the lacking authorisation, the official had not represented the Finnish State and thus not been competent to issue a warning. This seems contradictory. In order to assess the accountability of the Finnish State, the Court refers to the semblance of the situation; in order to examine whether the state was legitimated, by contrast, it refers to the actual legal situation resulting from the lack of authorisation. For the sake of regulation and for the sake of the internal market, the Court therefore sacrificed its interest in health protection.

Representing Finland, Mr. Lehtinen should also have been legitimated to ascertain the dangerousness of the lifts. In this case, the requirements of Art. 11.1 MD would have been fulfilled, so that without any margin of discretion, Finland would have been forced to adopt measures. Notwithstanding the above, at least in cases where machinery definitely poses a 'serious risk,' any margin of discretion

¹²² *Ibid.*, para 72.

¹²³ *Ibid.*, para 68.

conferred on the Member States by Art. 11.1 MD (“where a Member State *ascertains*...it shall take”) should be reduced to zero.¹²⁴

It finally surprises that although various Member States were affected by the lifts, Finland was the only Member State who actually took action (and this even involuntarily).¹²⁵

ii. Information systems (EWRS, RASFF and RAPEX)¹²⁶

The efficient and fast exchange of information about risks is crucial to avert (further) damage. In case of the E. coli bacteria crisis, Germany and the Commission issued several notifications through the warning systems and held daily audio-conferences, which involved a large number of European bodies.

(1) Information about risks posed by food consumption goods may be exchanged via the confidential Early Warning Response System (EWRS) and the Rapid Alert System for Food and Feed (RASFF). Both involve the Member States and the Commission; the RASFF additionally includes the European Food Safety Authority (EFSA), which monitors and analyses the risks.¹²⁷ Via the systems, the participants communicate any direct or indirect risk to human health¹²⁸ (RASFF), respectively any communicable disease listed in the Annex (EWRS).¹²⁹ An obligation to do so, however, only exists if the risks are ‘serious’ or if the participants (plan to) adopt measures.¹³⁰

In the E. coli bacteria crisis, the exchange of information through the EU warning systems played a vital role; the Commission even admonished the German representative to use the official channels and emphasised that the RASFF notifications ensured the traceability of products.¹³¹ In order to inform the EU of the ongoing outbreak, the German authorities first issued a EWRS report and subsequently, a RASFF notification concerning cucumbers from Spain (like the Commission), which they withdrew, when no bacteria with the specific serotype could be detected. Later, they issued another RASFF warning against the STEC-contaminated organic sprouts mixture from Germany and on 25 June 2011, finally France issued a notification concerning the fenugreek seeds imported for sprouting from Egypt (packaged in the United Kingdom, via the Netherlands and via Germany).

¹²⁴ In German law called “Ermessenreduktion auf Null,” see, e.g., Laub, *Ermessenreduzierung in der verwaltungsgerichtlichen Rechtsprechung*, 2000, p. 50.

¹²⁵ A.G.M. stated that in consequence of the acts of Mr. Lehtinen and the Ministry, in various European countries, its turnovers had fallen substantially, see Opinion of Advocate General Kokott in *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03) [2007], para. 45.

¹²⁶ See, e.g., Heussner 2007; Brecke 2000.

¹²⁷ See Art. 35 Foodcode.

¹²⁸ See Art. 50.1 Foodcode.

¹²⁹ See Art. 1 Decision No 2119/98/EC; however, by listing the specific diseases, the legislator indirectly limits the application to serious risks.

¹³⁰ See Art. 50.2, 50.3 Foodcode, Art. 6.2 Decision No 2119/98/EC of the European Parliament and the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community, OJ L 268, 3.10.1998, p. 1 [hereinafter referred to as Decision No 2119/98/EC].

¹³¹ Audio-conference 07 June 2011.

Nonetheless, huge parts of the communication took place outside the information systems, as almost up to the very end of the outbreak, the authorities had to deal with mere suspicions. Thus, a lack of verification complicates the issuance of (public) RASFF notifications significantly. Although the system facilitates a fast, efficient and relatively reliable exchange of information, the notifications do not provide detailed information on sampled products or used methods for the analysis. They specify neither the origin nor the brand of a product, nor do they name the producers, distributors or importers. Instead, they merely inform about the countries affected, the specific type of product and, if available, any test results. Warnings thus are not only publically accessible but also very broad. In the audio-conferences, the bodies could exchange a lot more (pending) information in less time and without attracting as much public attention. In particular, they could share their collected statistical data and inform the participants about all products already ruled out. The other EU bodies and Member States could use this information not only to scrutinize the German findings and research methods¹³² but also to add own remarks and observations. In fact, only in these conferences, moreover, bodies of experts not (directly) involved in the warning systems could be consulted, such as the European Centre for Disease Prevention and Control (ECDC), the EU Laboratory for E. coli bacteria, or the WHO.

(2) Information about non-food risks regularly may be exchanged via the Rapid Exchange of Information System (RAPEX) (Art. 10.1 GPSD). It involves, just as EWRS and RASFF, the Commission and the Member States, however, does not include any authority similar to EFSA that ensures the smooth functioning of the system. Information to be exchanged concerns, i.a., the risk assessment, the dangerous products, the test methods and results, recent scientific developments as well as other aspects relevant for control activities (Art. 10.2 GPSD). Different from RASFF, RAPEX therefore discloses the brands of the risk-posing products and even provides pictures and barcodes.¹³³ Interestingly, it exclusively covers *serious* risks however;¹³⁴ these must be notified regardless whether the adoption of measures is planned or not (Art. 12.1 GPSD);¹³⁵ normal risks, by contrast, must not be notified.

¹³² Spain and the EU Laboratory for E. coli bacteria, for instance, requested more information as regards the origin of the underlying samples and the methods used for the sampling, see Audio-conference 07 June 2011.

¹³³ See point (3) of Annex II GPSD: “Member States notifying under Article 12 shall provide all available details. In particular, the notification shall contain the information stipulated in the guidelines referred to in point 8 and at least: (a) information enabling the product to be identified; (b) a description of the risk involved, including a summary of the results of any tests/analyses and of their conclusions which are relevant to assessing the level of risk; (c) the nature and the duration of the measures or action taken or decided on, if applicable; (d) information on supply chains and distribution of the product, in particular on destination countries.”

¹³⁴ See Art. 12.1 and point (1) of Annex II GPSD; for more information about ‘serious risks’ see below.

¹³⁵ If a Member State adopts or plans to adopt measures in case of normal risks, this must be notified to the Commission (Art. 11.1 GPSD). However, there is no obligation to notify the other Member States.

iii. The Commission—guardian of the internal market¹³⁶

(1) The Commission is not only responsible for the management of RASFF but also promotes and takes part in the operation of RAPEX; it is thus a central actor in the handling of European risks.¹³⁷ Whenever measures could possibly hinder the internal market, they must be notified to the Commission,¹³⁸ which then forwards the received information to the relevant bodies and Member States and acts as a mediator.¹³⁹ Where it is evident that food is even *likely* to constitute a ‘serious risk’ and such risk “cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned,” the Commission *shall immediately* adopt measures.¹⁴⁰ If this risk originates from non-food consumption goods, however, the Commission is merely entitled (“may”) to *require the Member States* to take measures, and this only under strict conditions, e.g. when from prior consultations emerges that the Member States differ significantly on the approach to deal with the risk.¹⁴¹

With regard to machinery, the Commission competences are even more restricted. Thus, for risk-posing machinery not complying with a harmonised standard, as it was the case with the vehicle lifts, the Commission has no competence to intervene at all. Instead, it simply considers whether the measures taken by a Member State were justified.¹⁴² Likewise, for ‘potentially hazardous’ machinery that nevertheless complies with a harmonised standard, the Commission cannot take measures itself; instead, it *may* require the Member States to do so, e.g., to prohibit or restrict the placing of the machinery on the market or to make such machinery subject to special conditions.¹⁴³ If, apart from that, a Member State or the Commission considers a harmonised standard as not entirely satisfying the essential health and safety requirements, it shall bring the matter before the committee set up by Directive 98/34/EC.¹⁴⁴

(2) During the crisis in 2011, the Commission dominated and coordinated the proceedings, issued warnings and increasingly exerted pressure on Germany. By organising the audio-conferences, it provided a platform for the Member States and the EU bodies to exchange information but also to voice concerns and complaints. The Commission itself expressed several times its concerns about the management of the crisis and the low number of total samples compared to the severity of the

¹³⁶ The Commission undertakes an automatic review of all measures adopted by Member States that are not local in effect, whether or not they are emergency measures, Hodges 2005, p. 171.

¹³⁷ See Art. 50.1 Foodcode, Art. 10.1 GPSD.

¹³⁸ See, e.g., Art. 50.2 (1), 50.5 Foodcode, 11.1 GPSD, 11.2 MD, Art. 14.1 MD. Member States also must inform the Commission if they are of the opinion that measures taken by another Member State are incompatible with the Foodcode or ‘likely to affect’ the internal market, Art. 60.1 Foodcode.

¹³⁹ See, e.g., Art. 50.2 (2), 30.3 Foodcode, 11.2 GPSD, 11.3 MD.

¹⁴⁰ See Art. 53 Foodcode.

¹⁴¹ See Art. 13 GPSD.

¹⁴² See Art. 11.3 MD.

¹⁴³ See Art. 9 MD.

¹⁴⁴ See Art. 10 MD.

outbreak. In particular, it emphasised that the newly developed PCR methods¹⁴⁵ should enable a much more rapid processing of the samples.¹⁴⁶ For this reason, the Commission was heavily committed to getting the ECDC even more involved in the risk analysis. Although according to the German RKI representative, one of the Centre's experts had already arrived, it requested the ECDC to be prepared for a mission together with the EFSA and the DG SANCO to assist, help and verify the ongoing investigations; a collaboration was essential and had to be enforced.¹⁴⁷ The ECDC should suggest the best practices on the treatment of STEC cases to develop a common guidance document. On top of that, the Commission requested Germany to report twice a day on the cases and the result, whereupon the representative of the RKI responded with restraint; the national notification system was not that fast, so that more reports would not provide additional information.

After the end of the outbreak, the Commission launched promotion activities and a media campaign to rebuild the trust of consumers in the fruit and vegetables sector.

iv. The European Food Safety Authority (EFSA) and the European Centre for Diseases Prevention and Control (ECDC)¹⁴⁸

(1) In case of health threats posed by foodstuff, the European Food Safety Authority (EFSA) and the European Centre for Diseases Prevention and Control (ECDC) promote scientific analyses and therefore have extensive powers to collect respective data from the Member States. Furthermore, they support the communication between the actors on EU level.

The EFSA was established with the Foodcode in 2002 and is supposed to contribute to a 'high level of protection of human life and health.'¹⁴⁹ It consists of the Management Board, the Executive Director, the Advisory Forum, the Scientific Committee and the Scientific Panels. Its task is to issue scientific opinions at the request of the Commission, of the European Parliament or of the Member States, but also on its own initiative.¹⁵⁰

The ECDC was established in 2005 and aims at strengthening Europe's defences against infectious diseases.¹⁵¹ "[T]he Centre shall...identify, assess and communicate current and emerging *threats* to human health from communicable diseases. In the case of other outbreaks of *illness of unknown origin*

¹⁴⁵ The polymerase chain reaction (PCR) is a method to reproduce DNA, see Polymerase chain reaction 2014.

¹⁴⁶ Audio-conference 02 June 2014.

¹⁴⁷ Audio-conference 02 June 2014.

¹⁴⁸ Similar European bodies responsible for non-food risks are the Scientific Committee on Consumer Safety (SCCS) and the Scientific Committee on Health and Environmental Risks (SCHER). The latter only act at request of the Commission, see Art. 2 Commission Decision 2008/721/EC of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC, 10.9.2008, OJ L 241.

¹⁴⁹ See Art. 1.2 (2), 22.1 and Art. 22.3 Foodcode.

¹⁵⁰ See Art. 29.1 Foodcode.

¹⁵¹ Mission ECDC 2014.

which may spread within or to the Community, the Centre shall act *on its own initiative* until the source of the outbreak is known.”¹⁵² Hence, at least in case of a communicable disease, also the ECDC does not depend on Commission requests; it may even ask the Member States to support its work, e.g., by providing data.¹⁵³

Both, EFSA and ECDC, seek to maintain scientific excellence and are in principle independent.¹⁵⁴ For the composition of the EFSA Management Board, the Commission draws up a list, from which then the Council in consultation with the European Parliament appoints fourteen members.¹⁵⁵ The members have to be selected in such way as to ensure the highest standards of competence, a broad range of relevant expertise and the broadest possible geographic distribution.¹⁵⁶ For the ECDC Management Board, in addition to the European Parliament and the Commission, also each Member State appoints one member.

Likewise, the Advisory Forums of both,¹⁵⁷ which give advice to the (Executive) Directors,¹⁵⁸ are composed of representatives from the competent Member State bodies¹⁵⁹ as well as of three members without voting rights, which are nominated by the Commission. Merely, the Scientific Committee and the Scientific Panels of the EFSA¹⁶⁰ are composed of independent scientific experts.¹⁶¹

(2) From the German EWRS notification on, EFSA and ECDC attended all audio-conferences on the outbreak and played a decisive role in the shaping of an ‘EU opinion.’ The ECDC experts drew up an own risk assessment, as for which the RKI gave them full access to all relevant data¹⁶² and which they conducted in order to verify the German results. Yet, it seemed as if the Centre sought to reduce its responsibilities to a minimum.

In its utterances, the ECDC was much more reticent than the German representatives were. On 25 May 2011, for instance, because of statistical data they had collected from sick persons, the German RKI and the Public Health Authority Hamburg publically recommended as a precaution not to consume raw tomatoes, cucumbers or leaf salad from Northern Germany.¹⁶³ The ECDC, by contrast, in the

¹⁵² See Art. 3.1 (1), (2) Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control, OJ L 142, 30.4.2004, p. 1 [hereinafter referred to as Founding Regulation] (Italics added by the author).

¹⁵³ See Art. 4 Founding Regulation.

¹⁵⁴ See Art. 1.1, 6.1, 6.2 Founding Regulation, Art. 25.1, 37 Foodcode.

¹⁵⁵ See Art. 25.1 Foodcode.

¹⁵⁶ See Art. 25.1 Foodcode, Art. 14.2 Founding Regulation.

¹⁵⁷ See Art. 27.3 Foodcode, Art. 18.3 Founding Regulation.

¹⁵⁸ See Art. 26.1 Foodcode, Art. 17 Founding Regulation.

¹⁵⁹ See Art. 27.1 Foodcode, Art. 18.1 Founding Regulation.

¹⁶⁰ See Art. 28.1 Foodcode.

¹⁶¹ See Art. 28.4 Foodcode.

¹⁶² ECDC Rapid Risk Assessment Outbreak of Shiga toxin-producing E. coli (STEC) 2011.

¹⁶³ Joint Opinion of the Federal Institute for Risk Assessment and the RKI of 25 May 2011.

audio-conference on 26 May 2011, declared that the source was still unknown, although cucumbers could be one possible source, as 88 % of the persons affected had consumed them.¹⁶⁴ In doing so, the ECDC not only gave little support to the German authorities and relinquished actually to *assess* its scientific findings, but also backed off from proposing any (precautionary) measures. In its own interpretation, the task to assess and communicate the threat seemed not to include precautionary, strategic or political considerations; in particular, it completely left the decision on the adoption of measures to the Commission and the Member States. Likewise, when being approached to develop a common guidance document for general practitioners, the Centre stated that its legal mandate would not cover the development of guidelines on its own.¹⁶⁵

In fact, every risk assessment goes beyond a mere scientific evaluation however. On the one hand, a hazard¹⁶⁶ always constitutes merely one aspect of a risk: only when being combined with a certain level of severity and probability, it becomes a risk.¹⁶⁷ Thus, expert appraisals not only evaluate a danger scientifically, they inevitably also place scientific findings in context. On the other hand, although the steps vary according to the legal act,¹⁶⁸ principally, in all areas, the assessment of risks follows the same strategy: the competent bodies gather all relevant facts, analyse and assess them, and decide, where appropriate, on the adoption of (precautionary) measures. A clearly defined distinction between these steps has been criticised as artificial and difficult to maintain in practice.¹⁶⁹ Alemanno (2008) states,

“whilst the generally accepted *summa divisio* between the decision-making responsibility of political institutions and the purely advisory role of expertise rests upon the assumption that risk analysis can be divided into a wholly scientific process of analysing the facts and a political process, this distinction has increasingly been doubted through time.”

The assessment of a risk therefore always also includes a decision (not) to adopt measures. In the E. coli bacteria crisis, the ECDC tried to abdicate this responsibility. The German authorities, by contrast,

¹⁶⁴ Audio-conference 26 May 2011.

¹⁶⁵ Audio-conference 2 June 2011.

¹⁶⁶ The use of the term varies depending on the legal act: according to Art. 3 No. 14, “‘hazard’ means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;” the GPSD uses the term ‘dangerous,’ see, e.g., Art. 2 (c) GPSD.

¹⁶⁷ Art. 3 No. 9 Foodcode describes ‘risk’ as “a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.”

¹⁶⁸ The Foodcode describes ‘risk analysis’ as a process consisting of three interconnected components: risk assessment, risk management and risk communication, see Art. 3 No. 10 Foodcode; the officials identify the hazard and characterise the risk on a scientific base, they weight policy alternatives, and finally, they exchange all kind of information, see Art. 3 No. 11-13 Foodcode. The GPSD only speaks of ‘risk assessment’—without providing any tighter definition, see, e.g., Art. 10.2 (a) GPSD. Following the legal acts, also the literature uses the terms in an inconsistent manner, see, e.g., Schütz et al. 2006, pp. 13 ff; Bris et al. (eds.) 2012; Yoe 2012, pp. 4 ff. or Theodore & Dupont 2012, p. 11.

¹⁶⁹ See, e.g., Alemanno, JMWP 18/08, p. 9.

seemed relieved when they finally could take action, i.a., because regulatory responses often serve to convince the public that a problem is well controlled—particularly in food crises.¹⁷⁰

d. The addressees

(1) The main addressee in the GPSD is the ‘producer.’¹⁷¹ For the purpose of the Directive, this means primarily the manufacturer of the product, see Art. 2 (e) (i). The importer, by contrast, is only obliged in second place; the GPSD refers to him, if the manufacturer is not established in the Community, Art. 2 (e) (ii). Since the distribution activity does not affect the safety properties of a product, the distributor is no producer;¹⁷² nevertheless, the GPSD also assigns some relatively weak obligations to him, e.g., to help to ensure the compliance of a product, however, without being obliged to examine the latter.¹⁷³

The MD lays great stress upon the manufacturer,¹⁷⁴ who designs and/or manufactures the machinery, see Art. 2 (i) MD. It neither mentions the importer nor the distributor. However, Art. 11.1 MD, which entitles the Member State to intervene if machinery with a CE marking is liable to compromise the health and safety of consumers, does not specify an addressee; rather, the Member State has to take all appropriate measures to prohibit the placing and/or putting into service, to restrict or to withdraw the machinery from the market.

In case of the vehicle lifts, the importer Pörhön Tuontiliike played the most important role. Before being notified of the safety doubts by the Ministry, in course of the market supervision procedure, it attended several meetings with the health and safety district office Vaasa. Moreover, not the manufacturer but an representative of the importer joined the meeting with Mr. Lehtinen and the competent administrator Mr. Kanerva on 20 December 2000, in which the compliance of the new locking system was approved. Likewise, the interview in the national television channel on 17 January 2001 was conducted with Mr. Lehtinen and a representative of the importer. Contact person during the whole proceedings thus was the market participant easiest to reach: the importer.

¹⁷⁰ See Brannigan 2011, p. 112, who moreover highlights the differences between ‘forensic’ and ‘normal’ science—particularly in the public perception. To convince the public that a problem is well-controlled, the authorities particularly emphasise all those facts that support their analysis, as precisely these are critical to a positive social response, see *Ibid.*

¹⁷¹ See, e.g., Art. 3.1 GPSD: “Producers shall be obliged to place only safe products on the market.”

¹⁷² See Art. 2 (f) in conjunction with Art. 2 (e) (iii) GPSD.

¹⁷³ See, e.g., Art. 5.2 (1) GPSD: “Distributors shall be required to act with due care to help to ensure compliance with the applicable safety requirements, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with those requirements.” (Italics added by the author)

¹⁷⁴ See, e.g., Art. 5.1 MD.

The Italian manufacturer A.G.M. gained knowledge about the deficiencies only from the Finnish importer. Subsequently, it designed a new locking system for the vehicle lifts, however, without changing the front lifting arms. After the issuance of the various warnings by Mr. Lehtinen, it claimed compensation from the Finnish State and from Mr. Lehtinen for the damage caused to its business.

(2) Without attaching more importance to one of them, the Foodcode places duties on all operators, from the producer to the distributor, regardless of whether or not the product was placed on the market.¹⁷⁵ Even products *imported* to the Community *for* placing on the market must comply with the requirements, see Art. 11 Foodcode.¹⁷⁶

The main efforts in the E. coli crisis aimed at finding the source of the outbreak, and only in second place at the adoption of measures. When the German authorities finally identified with great certainty the organic vegetable farm in Bienenbüttel (Germany) as the starting point of the outbreak, they first banned the sale of its sprouts and eventually of all its vegetables. Almost one month after, the Commission decided that all fenugreek seeds imported into the EU between 2009 and 2011 had to be taken from the market, examined and destroyed; furthermore, on certain types of seeds, it imposed an import ban until the 31 October 2011. Addressees of the measures thus were indeed even-handedly all producers, importers and distributors of fenugreek seeds and sprouts whose products had possibly been exposed to the contaminating STEC bacteria.

e. The scope

The level of protection differs, i.a., depending on the point in time the legal act refers to as ‘starting point’ of its regulation (*i.*), the definition of the product to be regulated (*ii.*) and the aimed level of protection (*iii.*).

i. The scope of the legal act in the narrower sense (starting point)

(1) In its scope, the GPSD includes all products that are used by consumers, even when they are not intended to be used, Art. 2 (a) GPSD; nevertheless, the application of the Directive presupposes the placement of the products on the market, Art. 3.1 GPSD. Hence, the control and protection mechanisms are not set into motion before the products have not been placed on the market; prior to that, the manufacturers etc. are not subject to any obligation.

¹⁷⁵ Art. 17.1 Foodcode: “Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.”

¹⁷⁶ Art. 11 Foodcode: “Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.”

The question arises as when a product is placed on the market within the meaning of the GPSD.¹⁷⁷ The legal act itself does not give a definition. As can be seen in the producer's obligation to only place safe products on the market, however, the Directive proceeds on the assumption that in any case there is a temporal caesura between the production and the placement of a product on the market. Without legal force, the Blue Guide of the Commission explains,

“Placing a product on the market requires an offer or an agreement (written or verbal) between two or more legal or natural persons for the transfer of ownership, possession or any other property right concerning the product in question. This transfer could be for payment or free of charge. It does not require the physical handover of the product.”¹⁷⁸

This goes along with the very vague definition of the term in Regulation 765/2008;¹⁷⁹ there it says in Art. 2.2., “For the purposes of this Regulation the following definitions shall apply:... 2. ‘placing on the market’ shall mean the first making available of a product on the Community market.” The import of a product, hence, does not necessarily implicate its ‘placing on the market.’

The application of the MD, on the other hand, neither depends on the placement of the product on the market nor on the use by consumers or workers. Instead, in order to confine its applicability, the MD focusses on the term ‘machinery.’

(2) The Foodcode explicitly applies to all stages of production, processing and distribution of food and feed, Art. 1.3 Foodcode; excluded is merely the private production. Hence, here again, the placement of the product on the market does not matter for the application of the Regulation; rather, the Foodcode aims to attack risks at the earliest possible moment.¹⁸⁰ This is also reflected in Art. 11, which explicitly extends the safety requirements to products imported into the Community.

In the E. coli bacteria crisis, the authorities could not take advantage of this legal opportunity to intervene early. Indeed, the risk-posing sprout seeds were imported to Germany already in 2008. Until 08 May 2011, however, their contamination with STEC bacteria remained undetected, as only then, several people fell sick from sprouts they had consumed and that had been acquired from contaminated seeds. Since in Germany all types of E. coli bacteria are notifiable as part of the usual monitoring procedures, see 7.1 (1) 13.a IfSG,¹⁸¹ it is to be believed that shortly after their occurrence

¹⁷⁷ Imports are particularly problematic in this context; on their significance, see Wiebauer, EuZW 2012, 14.

¹⁷⁸ Blue Guide of the Commission 2014.

¹⁷⁹ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, 13.08.2008, OJ L 218.

¹⁸⁰ See Recital (10) Foodcode: “Experience has shown that it is necessary to adopt measures aimed at guaranteeing that unsafe food is not placed on the market... .”

¹⁸¹ The German Protection against Infection Act: Infektionsschutzgesetz (IfSG), 20 July 2000, BGBl. I p. 1045.

on 08 May 2011, the cases were reported to the health service. Nevertheless, only after the first person had died,¹⁸² on 22 May 2011, the German health services as well as the Commission eventually launched alert systems at local, national, EU and international level, i.a., by issuing an EWRS report.¹⁸³ In the following, the public health and food safety authorities of the Member States and the relevant European risk assessment agencies got involved, namely the EFSA, the ECDC, the EU-RL for E. coli bacteria, the DG SANCO and the Health Security Committee.¹⁸⁴ Furthermore, a team of experts from the RKI undertook further investigations in Hamburg, where the cases had occurred. It took the involved bodies almost three months before they could terminate the outbreak on 26 July 2011. Hence, despite the early and ample applicability of the Foodcode, the authorities started their risk analysis more than two years after the risk ‘had been given rise to’ and two weeks after the first case of illness had occurred.¹⁸⁵

ii. Definition of the product to be regulated

(1) It is crucial moreover, how the legal act defines the product to be regulated; by this means, it easily restricts its scope. The GPSD ‘defines’ the term ‘product’ very wide; the Directive concerns de facto any product likely to be used by consumers.¹⁸⁶ Excluded are merely those second-hand products that were supplied as antiques or as products to be repaired or reconditioned prior to being used. This wide definition illustrates the Directive’s function as a general legislation for all consumer products not or not completely covered by sector-specific legislation.

The MD applies to all kind of (partly completed) machinery, see Art. 1.1 (a) and (g),¹⁸⁷ which it defines as any assembly (intended to be) fitted with a drive system and consisting of linked parts or components, at least one of which moves, see Art. 2 (2) (a).¹⁸⁸ It is partly completed, when the

¹⁸² Aggressive EHEC-Form sorgt für Todesfälle 2011.

¹⁸³ Commission Staff Working Document Lessons learned 2011.

¹⁸⁴ Flash Report of the European Commission 2011.

¹⁸⁵ The use of the term ‘risk analysis’ is uneven. I refer to the definition in Art. 3.10 Foodcode, which says, “For the purposes of this Regulation:... 10. ‘risk analysis’ means a process consisting of three interconnected components: risk assessment, risk management and risk communication.” (See below)

¹⁸⁶ Art. 2 (a) GPSD provides, “For the purposes of this Directive: (a) ‘product’ shall mean any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned. This definition shall not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect.”

¹⁸⁷ Art. 1.1 MD states, “This Directive applies to the following products: (a) machinery; (b) interchangeable equipment; (c) safety components; (d) lifting accessories; (e) chains, ropes and webbing; (f) removable mechanical transmission devices; (g) partly completed machinery.” Art. 1.2 MD lists a number of exemptions from the provisions of Art. 1.1. ‘Where appropriate,’ the MD moreover even considers domestic animals and property as its subject matters, see Art. 4.1 and Art. 11.1 MD.

¹⁸⁸ The definition of ‘machinery’ is more complex. Art. 2 (2) (a) MD states, “The following definitions shall apply: (a) ‘machinery’ means: — an assembly, fitted with or intended to be fitted with a drive system other than

assembly is almost machinery but cannot in itself perform a specific application, and additionally, is only intended to be assembled with other machinery, whereby it forms machinery to which the Directive applies, see Art. 2 (2) (g).¹⁸⁹ Thereby, it excludes all single components from its scope, unless they build ‘partly completed machinery’ or are so-called ‘safety components,’ see Art. 1.1 (c), meaning that they fulfil a safety function for persons, are independently placed on the market, and are not necessary for the functionality of the machinery, see Art. 2 (1) (c) MD.¹⁹⁰

The MD therefore protected the vehicle lifts as of their partial completion, the GPSD as of their placement on the market. The exact dates for both events do not follow from the facts of the ECJ judgement; yet, the authorised Italian bodies inspected and certified type G 35 of the completed vehicle lifts in 1997. The lifts therefore had been in service for at least three years, when on 11 May 2000, the safety defects came to the Ministry’s notice.

(2) The Foodcode defines food as “any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans,” Art. 2 (1) Foodcode. Therewith, the Regulation accelerates the starting point of its application to such an extent that it even holds true for substances, raw ingredients and sub products.

Due to this wide scope, from the very moment of their import into the EU, already the contaminated sprout seeds were subject to the Foodcode’s regulatory content. If, hypothetically, the sprout seeds would have been subject to the regulation of non-food consumption goods, by contrast, only the cultivated sprouts would have legitimated the authorities to intervene; for the GPSD, even only after their placement on the market.¹⁹¹

directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application, — an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion, — an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure, — assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole, — an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;”

¹⁸⁹ The definition of ‘partly completed machinery’ is more complex. Art. 2 (2) (g) MD states, (g) ‘partly completed machinery’ means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies;

¹⁹⁰ “The following definitions shall apply:...(c) ‘safety component’ means a component: — which serves to fulfil a safety function, — which is independently placed on the market, — the failure and/or malfunction of which endangers the safety of persons, and — which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function...”

¹⁹¹ These are very hypothetical deliberations, but they are useful to illustrate the differences in the level of protection.

f. Aimed level of protection

(1) In both legal acts regulating non-food consumption goods, the legislator considers a level of safety below the highest possible as satisfying. On the one hand, the Recitals recognise consumer protection as beneficial for the internal market; on the other, they stress the special importance of the unity, consistency and limitation of the latter.

The GPSD aims to ensure ‘a high level of consumer protection.’¹⁹² However, the Directive pursues the health and safety protection first and foremost as a mean for the internal market; thus, a consistent high level of health protection preserves the consumers’ confidence and the unity of the internal market.¹⁹³ Beyond their utility for the internal market, however, the Directive restricts the protection endeavours, in order not to hinder the internal market.¹⁹⁴ The regulators of technical consumer goods are all too aware of this. They feel overregulated and restricted, although in their view, autonomy is substantial for an effective risk evaluation.¹⁹⁵ Acknowledging this insufficiency, they tend to develop their own management rules in the shadow.¹⁹⁶

Already in the Recitals, the focus of the GPSD on the market becomes apparent. The internal market sets the benchmark for the protection efforts. When mentioning disparities in terms of protection standards afforded to consumers, the Recitals regularly relate these deficiencies to the concomitant trade barriers and the distortion of competition.¹⁹⁷ For that reason, the GPSD does not only state the objective to protect consumers after the improvement of the internal market,¹⁹⁸ but also contemplates the health protection solely in the light of the internal market.¹⁹⁹ Moreover, to be regarded as ‘safe,’ a product must simply be ‘considered as acceptable and consistent’ with a high level of protection for the safety and health of persons, see Art. 2 (b) (1) GPSD. For the EU legislator, thus, economic concerns clearly stand in the centre of attention. Finally, the GPSD explicitly sets a ceiling for the health

¹⁹² See, e.g., also Recital (4) GPSD: “In order to ensure a high level of consumer protection, the Community must contribute to protecting the health and safety of consumers.”

¹⁹³ Recital (26) (1) reflects the correlation of both between the lines; it reads, “It is necessary, for the purpose of ensuring a consistent, high level of consumer health and safety protection and preserving the unity of the internal market, that the Commission be informed of any measure... .”

¹⁹⁴ Precisely for this reason, the law in general tends to spell out more and more the administrative and legal structures, see Micklitz & Roethe 1994, pp. 69/70.

¹⁹⁵ Micklitz & Roethe 1994, p. 69.

¹⁹⁶ See Micklitz & Roethe 1994, pp. 69/70.

¹⁹⁷ See, e.g. Recitals (3), (26) and (30) GPSD.

¹⁹⁸ See Recital (2) GPSD: “It is important to adopt measures with the aim of improving the functioning of the internal market, comprising an area without internal frontiers in which the free movement of goods, persons, services and capital is assured.”

¹⁹⁹ See Recital (3) GPSD: “In the absence of Community provisions, horizontal legislation of the Member States on product safety, imposing in particular a general obligation on economic operators to market only safe products, might differ in the level of protection afforded to consumers. Such disparities, and the absence of horizontal legislation in some Member States, would be liable to create barriers to trade and distortion of competition within the internal market.”

protection efforts. It states in Art. 2 (b) (2) GPSD, “The feasibility of obtaining higher levels of safety...shall not constitute grounds for considering a product to be ‘dangerous.’”

Equally obvious are these economic considerations in the MD. Recital (2) emphasises the importance of the machinery sector for the Community economy and the high social costs a large number of accidents occasions.²⁰⁰ The Directive thus puts the internal market in the centre and precisely from this perspective, acknowledges the significance of a certain level of protection. It requires solely the Commission to pursue a *high level* of health and safety protection, see Art. 9.3 MD;²⁰¹ the Member States, by contrast, merely have to ensure that machinery “does not endanger the health and safety of persons,” see Art. 4.1 MD.²⁰² Like the GPSD, it moreover provides a ceiling for the protection efforts; thus, e.g. Art. 6.1 MD provides that machinery complying with the MD requirements shall not be restricted.²⁰³

Following the MD, also the risk analysis of the vehicle lifts displayed a pre-eminence of the internal market: Firstly, the ministry refused unwaveringly the adoption of measures; secondly, the ECJ judgment declared the compensation of Member State failure to be in breach of law.

On the one hand, it was not sufficient for the Finnish Ministry (represented by Mr. Hurmalainen) that the dangerousness of the vehicle lifts was confirmed by the Vaasa health and safety district office, by the chief engineer of the Ministry (Mr. Lehtinen), by an administrator (Mr. Kanerva), by the Association of Technical Trades, and by the Metalworkers’ Union.²⁰⁴ Instead, despite these reports providing otherwise, the health and safety division of the Ministry declared in June that by that time, no factors had emerged obliging the Ministry to adopt measures against the manufacturer or the importer of the lifts.²⁰⁵ In a fax to the Central Association of Industry and Employers, the head of the health and safety division of the Ministry even argued that taking a measure that could disturb the working of the internal market did not seem reasonable to him, since only one accident had occurred in Finland, the

²⁰⁰ See Recital (2) MD: “The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Community economy. The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance.”

²⁰¹ See Art. 9.3 MD: “In the cases referred to in paragraph 1, the Commission shall consult the Member States and other interested parties indicating the measures it intends to take, in order to ensure, at Community level, a high level of protection of the health and safety of persons.”

²⁰² See also Recital (3) MD: „Member States are responsible for ensuring the health and safety on their territory of persons, in particular of workers and consumers and, where appropriate, of domestic animals and goods, notably in relation to the risks arising out of the use of machinery.”

²⁰³ See Art. 6.1 MD: “Member States shall not prohibit, restrict or impede the placing on the market and/or putting into service in their territory of machinery which complies with this Directive.”

²⁰⁴ See *AGM-COS.MET v Suomen valito/Tanno Lehtinen*, C-470/03, para. 21, 23, 26, 28, 32.

²⁰⁵ *Ibid.*, para. 34.

cause of which moreover was uncertain.²⁰⁶ In this connection it is worthwhile to mention that it moreover took the Ministry more than six months to draft a first report (Mr. Lehtinen, 27 November 2000) and another half a year to finalise its decision not to intervene (Mr. Hurmalainen, 14 June 2001), although during all this time, the vehicle lifts were at least supposed to be dangerous.

In the view of the evidential dangerousness of the vehicle lifts, the Finnish risk assessment thus might be classified as (an isolated case of) Member State failure; however, it is remarkable how vehemently the Ministry opposed the growing pressure to intervene.

Yet, what definitely reached effect far beyond the particular case was the subsequent ECJ judgment, which by stressing the conclusiveness of the MD revealed a politically and legally approved gap in the health protection to the benefit of the internal market.

(2) The Foodcode, too, mainly pursues “the free movement of safe and wholesome food” as an essential aspect of the internal market.²⁰⁷ Recital (2) stipulates, “A high level of protection of human life and health *should be assured in the pursuit of Community policies.*”²⁰⁸ Likewise, Art. 1 of the Foodcode states, “This Regulation provides the *basis* for the assurance of a high level of protection of human health and consumers’ interest in relation to food..., *whilst ensuring* the effective functioning of the internal market.”²⁰⁹ Yet, whereas both GPSD and MD only protect people’s health, the Foodcode additionally considers their well-being.²¹⁰

g. The burden of proof

Another important aspect is the allocation of the burden of proof. In both, GPSD and MD, the producer has to verify the safety of a product, before placing it on the market and/or putting it into service. The Foodcode, by contrast, imposes the burden of proof on the intervening Member State.

(1) Art. 3.1 GPSD provides, “Producers shall be obliged to place only safe products on the market.” Likewise, Art. 5.1 MD states, “Before placing machinery on the market and/or putting it into service, the manufacturer...shall: (a) ensure that it satisfies the relevant essential health and safety

²⁰⁶ Ibid., para. 29. He was probably referring to an accident that had occurred in March 2000 in Finland, when a camper van fell from an A.G.M. vehicle lift type G 32; according to AG Kokott, its deficiencies caused the accident, see Opinion of Advocate General Kokott in *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03) [2007], para. 27.

²⁰⁷ See Recital (1) Foodcode.

²⁰⁸ See Recital (2) Foodcode (Italics added by the author); see also Recital (10): “Experience has shown that it is necessary to adopt measures aimed at guaranteeing that unsafe food is not placed on the market and at ensuring that systems exist to identify and respond to food safety problems in order to ensure the proper functioning of the internal market and to protect human health.”

Similar issues relating to feed safety should be addressed.

²⁰⁹ Italics added by the author.

²¹⁰ See Recital (1) Foodcode.

requirements... ." Therefore, in both cases, the producer/manufacturer has to carry the burden of proof.

In the MD, however, this is alleviated by two presumptions. Firstly, machinery complying with a harmonised standard shall be presumed as complying with the essential health and safety requirements covered by such harmonised standard, see Art. 7.2 MD—even if in fact, this harmonised standard is insufficient. Secondly, machinery bearing the CE marking accompanied by the EC declaration of conformity shall be regarded as complying with the MD, see Art. 7.1 MD—even if the granting of the CE marking was unlawful. It is therefore cold comfort that with the CE marking, the manufacturer indicates that he takes responsibility for conformity of the product with the applicable requirements set out in Community harmonisation legislation, see Art. 1 (20) and Art. 30.3 Regulation (EC) No 765/2008.

(2) Here, the protection in the Foodcode is even weaker. It states in Art. 14.1, "Food shall not be placed on the market if it is unsafe." The Regulation therefore regularly expects foodstuff to be safe; only where there is proof that the foodstuff is unsafe, it must not be placed on the market. In particular, similar to the regulation in the MD, it must be deemed to be safe if it complies with specific Community provisions, Art. 14.7 Foodcode.²¹¹

h. The placement of 'safe' products

Since the legal acts aim to ensure the placement of 'safe' products, it is of special interest how they define 'safe.'

(1) A product is safe within the meaning of the GPSD, if it does not present any risk, Art. 2 (b) GPSD.²¹² If it poses a risk only under abnormal or not reasonably foreseeable conditions, or if the product could have been designed safer, this has no effect on its safety. 'Minimum risks' are considered acceptable.

The MD is more precise, however, does not provide a general definition of 'safe.' Before placing machinery on the market and/or putting into service, the manufacturer must meet many requirements, i.a., ensure that the machinery satisfies the relevant essential health and safety requirements set out in Annex I, affix a CE marking and draw up an EC declaration confirming the compliance of the machinery with the requirements, see Art. 5.1 MD.

²¹¹ Unless it is reasonable suspected to be unsafe, see Art. 14.8 Foodcode.

²¹² Art. 2 (b) GPSD: "[S]afe product' shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons... . The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be 'dangerous.'"

According to Annex I, “Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained *without putting persons at risk* when these operations are carried out under the *conditions foreseen* but also taking into account any *reasonably foreseeable misuse* thereof,” Annex I 1.1.2. (a) MD.²¹³ Therefore, in contrast to the GPSD, the MD in principle seeks to eliminate any (minimum) risk occurring under reasonably foreseeable conditions.²¹⁴

Therefore, before placing machinery on the market and/or putting it into service, the manufacturer has to certify the latter as complying with the Directive by affixing a CE marking, see Art. 12.1 MD in conjunction with Art. 5.1 (f).²¹⁵ The Directive distinguishes three situations. Firstly, if the machinery is not referred to in Annex IV MD, which covers, e.g., sawing machinery or vehicle servicing lifts, it has simply to be checked internally, see Art. 12.2 MD. If, secondly, the machinery is referred to in Annex IV MD, but does not comply with or is not covered by the relevant harmonised standard, the manufacturer must initiate either the EC *type-examination* procedure or the full quality assurance procedure, see 12.4 MD; both involve third bodies, which the manufacturer chooses freely from the bodies appointed by the Member States, see Art. 14, (2) of Annex IX, (2.1) of Annex X MD. Finally, thirdly, if the machinery is referred to in Annex IV MD *and* complies with the relevant harmonised standards, the manufacturer may choose between all three alternatives, 12.3 (a)-(c) MD. In conclusion, the Directive gives the impression of strict regulation, yet, completely relies on the manufacturer’s assessment on the classification.

The vehicle lifts produced by A.G.M. were defective. I.a. the test performed on behalf of the Ministry on 27 November 2000 demonstrated that the lift type G 35 did not comply with the essential health and safety requirements: thus, when loaded at the maximum and driven onto the least favourable direction, the front lifting arms bended. Both AG Kokott and Mr. Lehtinen considered the bending of the lifting arms as a breach of standard SFS-EN 1493, which according to them, required a structure of the system that could bear the maximum permitted load even in the least favourable lifting conditions and regardless of the direction in which the vehicle was driven onto the lift. In a later report on 12 February 2001, Mr. Lehtinen extended his concerns also to the vehicle lifts models G 28 and G 32. The shortcoming of the weak locking was resolved during the risk assessment procedure.

²¹³ Italics added by the author.

²¹⁴ These requirements are not unbreakable. Point (3) of Annex I MD, e.g., states, “[T]aking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.”

²¹⁵ The Member States shall consider a marking not to conform if the marked product is not covered by the Directive, the marking or the EC declaration is missing or an affixed marking is misleading, see Art. 17.1 MD. In these cases, they must oblige the manufacturer to make the product conform or, where non-conformity persists, take all appropriate measures to restrict or prohibit the placing on the market or to ensure that it is withdrawn, see Art. 17.3 MD.

The operating instructions the manufacturer provided with the vehicle lifts could not compensate this deficiency. Since the essential health and safety requirements only apply when machinery is used under the conditions foreseen by the manufacturer or in foreseeable abnormal situations,²¹⁶ the intended use has large effect on the assessment of the safety. To meet the requirements for the placing, the manufacturer must provide the necessary information, such as instructions, which define the intended use more closely.²¹⁷ Indeed, the instructions by A.G.M. stated that the precise maximum weight for a lifting operation depended both on the extension of the lifting arms and on the length of the arms loaded.²¹⁸ Thus, before the vehicles were lifted, the distances between the lifting arms as well as the axle weights stated in the registration book had to be ascertained; then, the vehicle had to be driven between the columns in such a way that the higher axle weight was borne by the short arms and the lower by the long arms. The MD, however, obliges the manufacturer to eliminate or reduce risks as far as possible, see point (1.1.2. (b)) of Annex I MD. As AG Kokott underlines, even against risks *that cannot be eliminated*, the manufacturer must take the necessary protection measures and only if these are not sufficient, s/he may merely inform users of the residual risks.²¹⁹ The risks resulting from the deficiencies of the vehicle lifts, by contrast, were remediable and instructions thus no appropriate mean to eliminate them.

Yet, as already in 1997, the Italian company ICEPI Srl, which was authorised by the Italian State and notified to the Commission, had certified the vehicle lifts type G 35, the lifts nonetheless had to be regarded as complying with the MD, see Art. 7.1 MD. Hence, particularly as according to the ECJ, no Member State had ascertained their dangerousness, the warning against the dangerous vehicle lifts issued by Mr. Lehtinen was unlawful.

(2) The Foodcode does not define ‘safe products’ either; instead, foodstuffs shall be deemed to be *unsafe* if they are considered to be injurious to health or ‘unfit for human consumption,’ Art. 14.2 Foodcode. Regard shall be had to the normal conditions of use as well as to the information provided to the consumer, see Art. 14.3. In the regulation of food consumption goods, therefore, also the well-being, e.g. affected by disgust, plays an important role.²²⁰ The food operators must not only comply with requirements ensuring the wholesomeness of foodstuffs, but also with requirements ensuring their fitness for human consumption, see Art. 14.5.

²¹⁶ See point (2) of Annex I MD.

²¹⁷ See point (1.1.1. (h)) of Annex I MD.

²¹⁸ See Opinion of Advocate General Kokott in *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03) [2007], para. 25.

²¹⁹ *Ibid.*, para. 62.

²²⁰ To give but one example, the meat adulteration scandal in 2013 illustrates the significance of disgust in food regulation; the public outrage was immense when instead of the advertised beef, foodstuffs contained undeclared or improperly declared horse meat non-hazardous to health, see, e.g. European Commission on Horse Meat 2014.

Both the fenugreek seeds imported from Egypt to a company in Lower Saxony (Germany) and the sprouts cultivated thereof were injurious to health and thus unsafe. The ill people who had consumed the STEC contaminated sprouts complained about initially watery and later bloody diarrhoea, abdominal pain, nausea, vomiting and in some cases about fever. During the crisis, throughout Germany, 3842 cases of infected persons were reported to the Robert Koch Institute (RKI); 855 cases were affected with the hemolytic-uremic syndrome (HUS), a severe complication of E. coli disease, which is characterized by kidney failure, impaired blood clotting and a destruction of the red blood cells. Fifty-three patients died.

i. The adoption of measures: obligations and powers

For the provided level of protection, it is moreover essential under which circumstances non-compliance obliges or even merely entitles the Member State authorities to intervene.

(1) (a) In the GPSD, authority actions are subordinate to actions taken by the producer or distributor. Even as regards the adoption of measures, the Directive attaches great importance to the self-regulation.

If products placed on the market are not safe, the producers are not obliged to take respective measures; according to the GPSD, they simply have to ensure that they are enabled to choose to take appropriate action, such as the withdrawal from the market, adequately and effectively warnings or the recall of the product from the consumers.²²¹ An obligation to adopt measures merely arises if the competent authority requests them to do so, see Art. 5.1 (5) GPSD.

The authorities themselves, however, may intervene only if the producers or distributors fulfil their obligations unsatisfactorily or insufficiently, see Art. 8.2 (3).²²² Therefore, before taking action, they first must request the producers to take action and wait for their non-compliance, see also Art. 8.2 (3) in conjunction with Art. 5.1 (5) GPSD. Subsequently, for evidentially dangerous products placed on the market, “if necessary,” the authorities shall ‘organise, order or coordinate’ withdrawals, alerts or recalls, see Art. 8.2 (3), 8.1 (f) GPSD.²²³ Although at first glance, the wording appears very strict (“shall”), the Directive therefore softens this obligation significantly by imposing two conditions: On the one hand, the producers or distributors must have fulfilled their obligations unsatisfactorily or insufficiently; on the other hand, an official intervention has to be ‘necessary.’ By giving priority to

²²¹ See Art. 5.1 GPSD.

²²² The compliance of a dangerous product with the general safety requirements does *not bar* the competent authorities from adopting measures, see Art. 8.2 (3) GPSD. For appropriate reasoning as regards the adoption of measures, see Art. 18.1 GPSD.

²²³ Art. 8.2 (3) GPSD: “If necessary, they shall organise or order the measures provided for in paragraph 1(f) if the action undertaken by the producers and distributors in fulfilment of their obligations is unsatisfactory or insufficient.”

actions of producers or distributors, the legislator accepts concomitant losses in time, which are borne by the quality of protection. Furthermore, the Directive incorporates a margin of discretion for the authorities and implies that unsatisfactory actions by the producers or distributors not necessarily justify an intervention.

If a Member State decides to intervene, it moreover must comply with Art. 8 Foodcode, which depending on the various situations and grades of dangers/risks, provides the legitimate measures. The Member State may, for instance, organise appropriate checks on any product, Art. 8.1 (a) (i), but impose bans only on a product that is ‘dangerous;’ a product merely suspected to be dangerous may be banned temporarily, Art. 8.1 (d)-(f). Only if the safety evaluations, checks and controls prove the dangerousness, the product may be banned permanently. Evidentially ‘dangerous’ products may even be withdrawn or recalled, see Art. 8.1 (f), (d) GPSD, albeit a recall must be the last resort, see Art. 8.2 (3) GPSD. Problems arise when the experts participating in the risk analysis are divided over the test results.

For products merely suspected to be dangerous, theoretically, the precautionary principle comes into play. Firstly, however, the measures in Art 8.1 (d) only leave little room for the application of the principle. Secondly, the Directive neither attaches particular importance to the principle nor provides a definition. In fact, it mentions the principle only once, in Art. 8.2 (1) GPSD, according to which, the authorities must implement the measures in a manner proportional to the seriousness of the risk *as well as take ‘due account’* of the precautionary principle. Hence, even measures adopted under the precautionary principle—and thus necessarily under conditions of high uncertainty—must be proportional to the seriousness of the risk. To be on the safe side, the authorities therefore regularly wait for the occurrence of serious damage before taking action.

(b) Likewise, the MD does not oblige the manufacturer to ensure the safety of a product, to withdraw or recall it. Instead, only where a Member State *ascertains* that under conditions reasonably be foreseen, such machinery is liable to compromise the health and safety of persons, domestic animals or property, the Member States *shall* take all appropriate measures to withdraw the machinery, to prohibit its placing or putting into service or to restrict its free movement thereof, see Art. 11.1 MD.

If a body responsible for the conformity assessment finds that machinery does not meet the requirements, it shall, taking account of the principle of proportionality, suspend or withdraw *the certificate or the approval* issued or place restrictions on it, unless compliance is ensured by the manufacturer, see Art. 14.6 MD.²²⁴

²²⁴ Italics added by the author.

(2) Food business operators explicitly remain fully accountable for the safety of their products, even after the placing of the latter on the market. Art. 19.1 Foodcode provides,

“If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it *shall immediately* initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.”²²⁵

Additionally, the Foodcode encourages the Member State authorities to intervene. Firstly, food law ‘shall be based’ on risk analysis, see Art. 6.1 Foodcode—a process consisting of three interconnected components: risk assessment, risk management and risk communication, Art. 3.10 Foodcode. This possibly also includes the adoption of measures.²²⁶ Moreover, Art. 14.8 Foodcode entitles the authorities to adopt measures even against unsafe food that complies with the food provisions. It states,

“*Conformity* of a food with specific provisions...*shall not bar* the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are *reasons to suspect* that, despite such conformity, the food is unsafe.”²²⁷

Consequently, already reasonably suspected unsafety suffices to justify an intervention, see Art. 14.8 Foodcode. Apart from that, wherever the *possibility* of harmful effects on health is identified but scientific uncertainty persists, according to the precautionary principle, provisional risk management measures may be adopted, see Art. 7.1 Foodcode. These measures, however, must be *necessary* to ensure the high level of health protection chosen in the Community and “shall be proportionate and

²²⁵ Italics added by the author.

²²⁶ The Foodcode defines the three components as follows, “11. ‘risk assessment’ means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation; 12. ‘risk management’ means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options; 13. ‘risk communication’ means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions,” see Art. 3.11-13 Foodcode).

²²⁷ Italics added by the author.

no more restrictive of trade than is required to achieve the high level of health protection..., regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration,” Art. 7.2 Foodcode.

During the crisis in 2011, almost from the very beginning of the investigations, the (German) authorities issued their warnings with reference to the precautionary principle. Already the first warning against cucumbers, tomatoes and leafy salad was explicitly a precautionary recommendation. Milk and meat had been ruled out as potential sources and statistics indicated that the majority of the sick persons had consumed cucumbers, tomatoes and leafy salad. Experts suspected 460 infections by this time, three of which had led to death.²²⁸ Likewise, the more concrete warning against Spanish cucumbers was based on statistics; thus, i.a., 88 % of the persons affected had consumed cucumbers. When finally, with a probability bordering to certainty,²²⁹ again statistics indicated that organic sprout mixtures from Bienenbüttel (Germany) had triggered the outbreak, also the third warning and the final ban were issued on base of the precautionary principle (the STEC bacteria could not be detected anymore).

The crisis showed that particularly food regulators very often are faced with likelihoods and prima facie evidences. Consequently, precautionary measures are of utmost importance. They however necessarily entail the risk of being adopted mistakenly, which is why their adoption regularly faces scepticism and resistance.

(3) The most contentious issue in both cases from practice was the adoption of public warnings.²³⁰ In fact, ensuring that consumers have sufficient and adequate information on the safety of the products is one of the core justifications for regulatory intervention based on the ‘market failure.’²³¹ Nonetheless, only the Foodcode places great value on the information of the public. Whereas neither GPSD nor MD explicitly mention the active furnishing of information,²³² the Foodcode states in Art. 10 (Public information),

“Without prejudice to the applicable provisions of Community and national law on access to documents, where there *are reasonable grounds to suspect* that a food or feed may present a

²²⁸ See, e.g., Ärzte kämpfen um immer mehr Leben 2011.

²²⁹ All infected persons had consumed sprouts originating from the respective sprout farm, see, e. g, EHEC: Kein Schadenersatz für Sprossen-Firma 2014.

²³⁰ A German sprout company, for instance, tried to claim compensation for the damage the warning against sprouts issued by the German Federal Institute for Risk Assessment had caused to its business, see LG Braunschweig, Judgement of 20 May 2014, 7 O 372/12.

²³¹ Hodges 2005, pp. 117, 27ff.

²³² The catalogue of measures in Art. 8 GPSD is exemplary. Art. 8.1 states, “For the purposes of this Directive, and in particular of Article 6 thereof, the competent authorities of the Member States shall be entitled to take, inter alia, the measures in (a) and in (b) to (f) below... .” The issuance of a public warning, therefore, may be one of the measures not explicitly mentioned. On the assurance of public access, see Art. 16.1 and Recital (35) GPSD.

risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities *shall take appropriate steps to inform* the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.”²³³

Hence, the Foodcode does not only oblige the public authorities to take action, but also defines the content of this information more closely (the nature of the risk, the food affected, the risk it may present as well as the measures taken or about to be taken).

j. Emergencies

All three legal acts barely regulate ‘emergencies.’ Neither the GPSD nor the MD mention them; only the Foodcode implements respective competences—yet, even in the latter, there is no legal definition and no obligation to act. Clearly, in emergencies, the regulation relaxes its strict requirements for an intervention; nevertheless, it leaves the reader in the dark about what to understand under the term ‘emergency’ and about the dispensable requirements compared to the normal state of affairs. It seems to be clear that emergency risks have to be ‘serious.’ The presence of an emergency, however, is largely bound to the assessment by the respective authorities, which evaluate the existence and the extent of a risk as well as the necessity of an intervention.

(1) The GPSD distinguishes ‘serious’ from normal risks²³⁴ and defines them as all serious risks that require rapid intervention by the public authorities, including those the effects of which are not immediate, see Art. 2 (d) GPSD.²³⁵ Hence, the Directive seems to distinguish between serious risks that require rapid intervention and those that do not. Even for the former, however, the Directive does not significantly facilitate an intervention; thus, also in case of ‘serious risks’ in the sense of Art. 2 (d) GPSD (those requiring rapid intervention), the adoption of measures is subject to strong restrictions. The competent authorities shall merely have the power to take the *necessary action in order to apply with due dispatch appropriate* measures such as those mentioned in 8.1 (b) to (f), see 8.3 (1) GPSD. The Member States shall determine these circumstances, assessing each individual case on its merits and taking into account the RAPEX guidelines, see Art. 8.3 (2) GPSD.

(2) The structure in the Foodcode is more complicated. Under the heading “Emergency measures for food...of Community origin or imported from a third country,” Article 53 Foodcode first states that the Commission shall immediately adopt measures, such as the suspension of the placing on the market,

²³³ Italics added by the author.

²³⁴ There is no such distinction in the MD.

²³⁵ Art. 2 (d) Foodcode: “‘serious risk’ shall mean any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities.”

if it is *evident* that a food is likely to constitute a *serious risk* that *cannot be contained satisfactorily by the Member State(s)* concerned. Yet, paragraph 2 provides,

“However, *in emergencies*, the Commission may provisionally adopt the *measures* referred to in paragraph 1 after consulting the Member State(s) concerned and informing the other Member States.”²³⁶

Thus, in fact, according to Art. 54.1, 53.2, in emergencies, *the Member States* may adopt interim protective measures *only after* having officially informed the Commission, and where the latter has not provisionally adopted measures itself. The legislator therefore acknowledges a need to transfer the primary competence from the Member States to the Commission.

Art. 53.2 only refers to the *measures* of paragraph 1 and thus, in principle, does not require evidence or seriousness. Recital (60) of the Foodcode states however,

“Recent food safety incidents have demonstrated the need to establish appropriate measures in emergency situations ensuring that all foods, whatever their type and origin, and all feed should be subject to *common* measures in the event of a *serious risk* to human health, animal health or the environment. Such a comprehensive approach to emergency food safety measures should allow effective action to be taken and avoid artificial disparities in the treatment of a *serious risk* in relation to food or feed.”²³⁷

In conclusion, not every serious risk therefore turns into an emergency (see Art. 53.1 Foodcode), but every emergency situation seems to deal with a serious risk.

(3) Likewise, in the legal research, precise definitions of an ‘emergency’ are rare. Scholars seem to have agreed upon some core properties, but mostly paraphrase or describe emergencies by using abstract terms or adducing individual characteristics.

According to Sorell (2002), “an emergency is a situation, often unforeseen, in which there is risk of great harm or loss and a need to act immediately or decisively if the loss or harm is to be averted or minimised.”²³⁸ Micklitz and Roethe (1994) point out that all those risks come under the category of emergencies that require speedy action on behalf of the authorities.²³⁹ They remark, however, that neither the legislator nor those who apply the law can tell in advance what an emergency is²⁴⁰—the identification of a case as an ‘emergency’ is the result of complex social procedure in which the parties

²³⁶ Italics added by the author.

²³⁷ Italics added by the author.

²³⁸ Sorell, PoAS 2002, p. 22.

²³⁹ Micklitz & Roethe 1994, p. 70.

²⁴⁰ Micklitz & Roethe 1994, p. 70.

involved weigh and measure ‘risks’, ‘dangers’ and ‘damage,’ in order to be able to decide whether it is an ‘emergency.’²⁴¹ Other researchers speak about ‘crises,’²⁴² ‘catastrophic risks’²⁴³ or ‘disasters’²⁴⁴ to describe emergencies, or else, explain that an emergency is characterised by the high level of uncertainty,²⁴⁵ the lack of suitable scientific evidence²⁴⁶ or the sudden occurrence.²⁴⁷ Some, moreover, find that emergency responses only take place *after* the event, meaning after the ‘catastrophe’ or the ‘disaster.’²⁴⁸

Emergencies completely change the regulatory approach. On the one hand, they are occasions for a serious rupture of moral conventions;²⁴⁹ in particular, in an emergency environment of high uncertainty, there is a great deal of room for political pressure to affect the outcome, especially by shifting the burden of proof.²⁵⁰ On the other hand, Fioritto and Simoncini (2011) stress that for emergencies, cost-benefit analysis are not the only methodology to assess the significance of a risk (anymore), since a mere mathematical or statistical analysis of probability does not overlap with the tolerability; instead, the regulatory concept needs to relate to the effectiveness of the regulation.²⁵¹

(4) This thesis defines emergencies as all situations of evident risks that due to potentially widespread and severe consequences for human health and/or well-being (for food risks)²⁵² require rapid intervention. Evidence is given in all cases where damage has occurred already or, considerably more seldom, where the occurrence is imminent.²⁵³

In most cases, before a risk may be qualified as emergency, severe damage, such as a fatality, has to occur, as precisely such damage proves the severity. Assured knowledge alone, by contrast, usually merely leads to an application of the rules for the normal state of affairs, e.g. to a regular recall of the

²⁴¹ Micklitz & Roethe 1994, p. 63.

²⁴² Brannigan 2011, p. 102.

²⁴³ Fioritto & Simoncini 2011, p. 118.

²⁴⁴ Alemanno 2011, xxii.

²⁴⁵ Brannigan 2011, p. 102.

²⁴⁶ Brannigan 2011, p. 102.

²⁴⁷ Fioritto & Simoncini 2011, p. 119; see also Briggs 2011, pp. 166/167.

²⁴⁸ Mitigation, by contrast, attempts to reduce the potential impact of a disaster *before* it strikes, see Alemanno 2011, xxii; see also Fioritto & Simoncini 2011, p. 115, according to whom, risk regulations offer protection beforehand, and emergency regulation generally applies *in the aftermath*.

²⁴⁹ Sorell, PoAS 2002, pp. 31/32; see also Viens (2011), p. 142, according to whom in emergencies, the features of a situation change significantly and can produce a corresponding change to the balance of normative reasons. Dyzenhaus (2011), pp. 21/22, even argues that to achieve efficiency in legal systems, emergency regulation cannot be limited by the rule of law; Schmitt 1922.

²⁵⁰ Brannigan 2011, p. 102.

²⁵¹ Fioritto & Simoncini 2011, p. 119. Likewise, Brannigan (2011), p. 102, states that in a crisis environment, principles can disappear under the weight of economic and political considerations.

²⁵² To mind comes here for example the meat adulteration scandal in 2013, which did not pose any risk to health, but affected the well-being by arousing disgust, see, e.g., European Commission on Horse Meat 2014.

²⁵³ One example of such imminent damage is the volcanic ash crisis in 2010, see, e.g., Governing Disasters 2011 by A. Alemanno (ed.).

risk-posing product. In respect of a certain source, on the other hand, evidence is dispensable; quite the contrary, as the E. coli bacteria crisis has shown, unidentifiable cases of illness not only suffice to trigger emergency responses but even spur them, as these cases visualize the imminent loss of control: bacteria spread fast and uncontrolled, while opportunities to contain them continuously shrink.

In fact, emergencies regularly require rapid intervention precisely because of this imminent loss of control. Additionally, however, this prerequisite clarifies that not every risk with potentially widespread and severe consequences requires rapid intervention; instead, there are also socially accepted risks, e.g. the usage of cars.

(5) In conclusion, it can be recorded that the assumption and the treatment of an emergency significantly depends on the risk regulators; these evaluate the existence and the extent of a risk as well as the necessity of an intervention. Particularly for emergencies, due to their unpredictability, it seems impossible to develop a legal pattern that covers all hypothetical situations appropriately. The actual lack of legal regulation therefore reveals precisely this general need for flexibility.²⁵⁴

²⁵⁴ Micklitz and Roethe (1994) identify negotiation in the shadow of the law as the most wide-spread solution to tackle safety problems, *ibid*, pp. 70, 73.

4. Searching for the reasons

a. Product safety as a tool of the market

Public health protection may be the most obvious purpose of product safety. Yet, due to its outstanding importance, in fact, the quality of the health and well-being protection essentially hinges on its interdependence with the European Single Market.

Alemanno (2008) considers, “...when called upon to regulate risks, the EU legislator is caught between two competing Treaty-sanctioned goals and must strike a balance.”²⁵⁵ Likewise, Armstrong and Butler (1998) declare that at the heart of any discussion of technical harmonisation lies the need to reconcile the demands of the free movement of goods with the need to ensure valued regulatory objectives, such as the protection of public safety or consumer and environmental protection.²⁵⁶

It is important to emphasise, however, that a certain level of health and well-being protection is essential for the proper functioning of the internal market. Therefore, the implementation of public health concerns taken by itself cannot lead to the conclusion that the legislator promotes them as opponent to the market. Instead, close inspection reveals that precisely their implementation (the way they were implemented) further underlines the superiority of the internal market.

(1) To ensure product safety and to implement respective control mechanisms is time-consuming and expensive, sometimes bars progress, and thus is a trade barrier. For this reason, market interests limit health protection efforts.²⁵⁷ In fact, balancing safety against costs is a traditional public policy function (Brannigan 2011),²⁵⁸ for which the regulator evaluates potential losses against potential benefits (Jachia and Nikonov 2011).²⁵⁹ Fioritto and Simoncini (2011), however, argue that the regulatory framework should engage in the process of mitigation only as long as the costs do not exceed the benefits, in order to provide a due level of protection only against those threats whose materialization would produce “intolerable effects for the affected community.”²⁶⁰ In their view, standards are a sound compromise between the necessity to ensure due protection against disastrous risks and their low probability of occurrence.²⁶¹

²⁵⁵ Alemano JMWP 18/08, p. 6. He also perceives a shift from the internal market-oriented product regulation towards a rather protection-oriented process regulation (p. 5, with further references).

²⁵⁶ Armstrong & Butler 1998, p. 145; see also Alemano, JMWP 18/08, p. 6; Zurek, YPES 2008, pp. 48/49.

²⁵⁷ See, e.g., Hodges 2005, p. 8; Brannigan 2011, p. 105; Fioritto & Simoncini 2011, p. 118; see also Wilke et al. 2012, who seek to work out a conceptual framework for economic assessment of the effectiveness of preventive measures for food safety improvement.

²⁵⁸ Brannigan 2011, p. 105.

²⁵⁹ Jachia & Nikonov 2011, p. 152.

²⁶⁰ Fioritto & Simoncini 2011, pp. 118/119.

²⁶¹ *Ibid.*, p. 130.

(2) For both—the internal market and the health and well-being protection—the legislator aims to harmonise safety requirements, as on both counts, regulatory failure in one Member State compromises the entire European market;²⁶² yet, whereas for the internal market the focus lies on the harmonisation, for the protection of consumers it lies on the assurance of a high-level protection. Acknowledging the need of EU-wide standards, Recital (3) GPSD, e.g., states,

“In the absence of Community provisions, *horizontal legislation of the Member States* on product safety, imposing in particular a general obligation on economic operators to market only safe products, *might differ in the level of protection* afforded to consumers. Such disparities, and the absence of horizontal legislation in some Member States, *would be liable to create barriers to trade* and distortion of competition within the internal market.”²⁶³

Nonetheless, both are also in a mutually profitable relationship. Thus, the protection of consumers greatly influences consumer behaviour and therefore is decisive factor for the proper functioning of the (internal) market.²⁶⁴ Shuibhne (2006) even classifies consumer protection rather as a market than a non-market concern, because it relates more to the demand than to the supply side.²⁶⁵ Firstly, the trust in the harmlessness of a product is essential condition for its selling, as in principle, consumers only buy products they can trust in; even for luxury or new goods, a feeling of safety increases buying interest. Secondly, official warnings not only inflict the market but also preserve the latter from wrong or outdated information. Counteracting harmful hoaxes, a reliable²⁶⁶ state warning system motivates consumers, if necessary, to build on public intervention and thus benefits the internal market. Likewise, Zurek (2012) recognizes that the regulation of the market is embedded in a certain society, in a way that both are interrelated and cannot function properly when being disconnected.²⁶⁷ She also claims, however, that paradoxically, various elements of the current European regulatory system are contrary to the declared goals of the Social Europe model.²⁶⁸

²⁶² See, e.g., Alemanno JMWP 18/08, p. 4.

²⁶³ Italics added by the author.

²⁶⁴ See, e.g., Zurek, YPES 2008, pp. 48/49, or Alemanno, JMWP 18/08, p. 5, who argues that in times of food safety crises and scandals, ‘protection’ is a *conditio sine qua non* for a proper functioning of the internal market.

²⁶⁵ Shuibhne 2006, p. 63; see also St. Clair Bradley (1999), p. 99, who states that a wide variety of measures, such as the horizontal harmonization of safety requirements for consumer products, may be adopted in pursuit of the proper functioning of the internal market.

²⁶⁶ The reliability is increased by the fact that governments largely depend on the will of the electorate, who takes great interest in its protection.

²⁶⁷ Zurek, YPES 2008, pp. 48/49.

²⁶⁸ See Zurek 2012, p. 25.

b. Health and well-being protection in EU primary law²⁶⁹

Already in EU primary law, health and well-being concerns play a rather minor part. The Treaties aim both to establish a functioning internal market and to protect the health and well-being of consumers—however, to completely different extents. A remarkable difference in the competence distribution illustrates the priority of the internal market and the function of the health protection as a mean for the latter. Hodges (2005), too, determines that the basis upon which the Community possesses competence to legislate in relation to product regulation is based almost exclusively not upon a policy of consumer protection or the achievement of a level of safety but upon the facilitation of trade.²⁷⁰

i. Limited powers and little obligations

Even though the TFEU indirectly states health protection as one of its objectives,²⁷¹ in fact, the implementation into the Treaty provisions is superficial and rather declaratory.

(1) The principle of conferral allows the EU to act only when the Treaties assign competence to the Union in the particular area; other than that, the competence remains with the Member States.²⁷² According to Art. 4.2 TFEU, shared competence applies, i.a., “in...(f) consumer protection...” and in “(k) common safety concerns in public health matters, *for the aspects defined in this Treaty.*”²⁷³ Therefore, the Treaties do allow the Union to adopt protection measures for the benefit of consumer health—however only as subject to very narrow conditions. Firstly, the measures must serve ‘common’ safety concerns, secondly, aspects defined in the Treaty must cover them and, thirdly, the adoption of measures must stand the subsidiarity principle. Therefore, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States²⁷⁴ and only in the pursuance of (other) aspects defined in the Treaty. The adoption of EU-wide approaches in public health matters is thus significantly exacerbated.

²⁶⁹ See, e.g., Reich 2014, Borges 2013, Hancher 2012.

²⁷⁰ Hodges 2005, p. 27.

²⁷¹ See, e.g., Art. 191.1 TFEU: „Union policy on the environment *shall contribute* to pursuit of the following *objectives*:...— protecting human health;” or Art. 114.3 TFEU: ““The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this *objective.*” (Italics added by the author)

²⁷² Art. 5 (2) Consolidated Version of the Treaty on European Union, 2010 O.J. C 83/01 [hereinafter referred to as TEU]: “Under the principle of conferral, the Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein. Competences not conferred upon the Union in the Treaties remain with the Member States.”

²⁷³ Italics added by the author.

²⁷⁴ See Art. 5.3 Consolidated Version of the Treaty on European Union, 2010 O.J. C 83/01 [hereinafter referred to as TEU] (italics added by the author).

(2) If the EU cannot justify a respective competence, it may merely support the Member States in their protection efforts, see Art. 6 TFEU.²⁷⁵ Even if being competent under Art. 4.2 (k) TFEU, however, the Union is not obliged to actually implement health protection measures.

Both consumer and health protection concerns shall merely be taken into account and only in the definition and implementation of all Union policies and activities.²⁷⁶ The Treaty therefore confines the assurance of a (high-level) protection to those areas in which the Union defines and implements other policies and activities; health protection alone cannot justify EU-wide actions.²⁷⁷

Even in the implementation of other policies, however, the Treaty does not ensure a minimum level of protection.²⁷⁸ In its proposals as regards the internal market, the Commission “will take as a base a high level of protection,” see Art. 114.3 (1) TFEU.²⁷⁹ The European Parliament and the Council, within their respective powers, will even only “seek to achieve” this ‘objective,’ see Art. 114.3 (2) TFEU. The pursuance of a ‘high level’ of protection in the European Union thus goes hardly beyond a declaration of intent. In fact, the provided level thus depends significantly on its utility for other policies, e.g., for the internal market.

Finally, the Treaties promote the well-being of consumers, but it is rather a commonplace when Art. 3.1 TEU says, “The Union's aim is to promote peace, its values and the well-being of its peoples.” A respective competence is not provided.

ii. The functioning of the internal market

Although it is recognised that the EU is competent for the establishment of an internal market, the allocation of such competence is controversial. By referring to the clear wording of Art. 4.2 f) TFEU,

²⁷⁵ See Art. 6 TFEU: „The Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States. The areas of such action shall, at European level, be: (a) protection and improvement of human health;... .”

²⁷⁶ Art. 9 TFEU: “In defining and implementing its policies and activities, the Union shall take into account requirements linked to the promotion of...a high level of...protection of human health;” Art. 168.1 (1) TFEU: “A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities;” Art. 169.1 TFEU: “In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests;” Art. 12 TFEU: “Consumer protection requirements shall be taken into account in defining and implementing other Union policies and activities.” See also Art. 35 (2) Charter of Fundamental Rights of the European Union, 2012 O.J. C 326/02, 402: “A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.”

²⁷⁷ Lister 1992, p. 7, points out that also the original Treaty of Rome regulated aspects of the foodstuffs field only in order to answer questions of the agricultural production or the free trade, that is to say, the elimination of trade barriers.

²⁷⁸ See also Art. 169.1 TFEU: “shall contribute to protecting the health.”

²⁷⁹ The Economic and Social Committee, too, has criticised this weak wording, see Opinion on Consumer Protection and Completion of the Internal Market, Economic and Social Committee, 91/C 339/08, OJ C399/16, 31.12.91.

many consider the adoption of respective measures as subject to shared competence between the Member States and the Union.²⁸⁰ Others strongly criticize the wording of Art. 4.2 f) TFEU as too wide and argue in favour of an exclusive EU competence by referring to Art. 114.1 and to Art. 3.1 (b) TFEU.²⁸¹ Art. 114.1 TFEU²⁸² in conjunction with Art. 26 TFEU²⁸³ empowers the European Parliament and the Council to adopt “the measures for the approximation of the provisions laid down...in Member States which have *as their object* the establishment and functioning of the internal market.”²⁸⁴ Art. 3.1 (b) TFEU moreover states, “The Union shall have exclusive competence in the following areas:...(b) the establishing of the *competition rules* necessary for the functioning of the internal market... .”²⁸⁵

In any case, the competence is not as restricted as the one concerning the adoption of health protection measures. In particular, it does not depend on the implementation of (other) EU policies. Even a justification under the subsidiarity principle is greatly facilitated, as in order to be effective, measures for the purpose of the European Single Market usually must be adopted all over Europe and thus exceed the territorial power of the Member States. Finally, Art. 3.3 (1) TFEU explicitly obliges the Union to establish an internal market and thereby boosts a respective competence.²⁸⁶

iii. Interpretation by the ECJ

Having said this, at first glance, some ECJ cases may surprise. Thus, in rare cases, the Court has emphasised that under certain circumstances “requirements of the protection of public health must

²⁸⁰ “Shared competence between the Union and the Member States applies in the following principal areas: (a) internal market... .”

²⁸¹ See, e.g., Advocate General Fennelly’s Opinion, *Germany v Parliament and Council* (C-376/98), 2000, I-8423, paras. 136, 142; Schwartz, AfP 1993, 409 (413); Ehlermann, *Integration* 1995, 11 (18 f.); Müller-Graff, *ZHR* 1995, 34 (66 ff.); Nettesheim, *EuR* 2004, 511 (532).

²⁸² Art. 114.1 TFEU: “Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall...adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.” (ex Article 95.1 TEC)

²⁸³ Art. 26 TFEU: “1. The Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market, in accordance with the relevant provisions of the Treaties. 2. The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties. 3. The Council, on a proposal from the Commission, shall determine the guidelines and conditions necessary to ensure balanced progress in all the sectors concerned.” (ex Article 14 TEC)

²⁸⁴ Italics added by the author.

²⁸⁵ Italics added by the author.

²⁸⁶ Art. 3.3 (1) TFEU: “The Union shall establish an internal market.”

take precedence over economic considerations.”²⁸⁷ According to Hodges, this approach is difficult to rationalize on the basis of the Treaty provisions.²⁸⁸

All of these cases, however, were concerned with food risks:

- the Order of the Court of Justice in Case C-180/96 *United Kingdom v. Commission* [1996] with the so-called ‘mad cow disease’ (bovine spongiform encephalopathy, ‘BSE’),
- the Judgment in Case C-183/95 *Affish v. Rijksdienst Keuring Veen en Vlees* [1997] and the Order of the Court of First Instance in Case T-136/95 *Industria del Frio Auxiliar Conserva v. Commission* [1998] with fishery products with serious shortcomings relating to hygiene and control in their production and storage conditions,
- and the Order of the President of the Court of First Instance in Case T-70/99 R *Alpharma v. Commission* [1999] with additives in feedingstuffs.

In its Judgments concerning non-foodstuff consumption goods, the Court was considerably more restrictive. For instance, in 2000, it struck down a Directive on tobacco advertising because the measure was in truth one of public health policy rather than market building.²⁸⁹

On the one hand, this again elucidates the outstanding position of food-related risks. On the other hand, it shows that under certain circumstances, risks can have so devastating effect that they harm the internal market. In these cases, health protection concerns must take precedence over ‘economic considerations’—these, however, are not synonymous with the internal market.

c. Not each product is the same: the predisposition of foodstuff risks

Some risks are particularly difficult to regulate i.e. those that we cannot control by our actions, those that pertain to phenomena that we can only partially understand with our senses, and those that can result in fatal outcomes (Jachia and Nikonov 2011).²⁹⁰ Foodstuff risks are predestined to have all three of these features.

(1) Firstly, toxic or contaminated foodstuffs extensively spread in all directions. Kapur and Smith (2011) argue that the modern global ‘food chain’ were much more like a matrix than a chain, especially when

²⁸⁷ Order of the President of the Court of First Instance in Case T-70/99 R *Alpharma v. Commission* [1999] ECR II-2027, para. 152; see also Order of the Court of Justice in Case C-180/96 *United Kingdom v. Commission* [1996] ECR I-3903, para. 93; Judgment in Case C-183/95 *Affish v. Rijksdienst Keuring Veen en Vlees* [1997] ECR I-4315, para. 43; Order of the Court of First Instance in Case T-136/95 *Industria del Frio Auxiliar Conserva v. Commission* [1998] ECR II-3301, para. 58; see also Hodges 2005, pp. 29/30.

²⁸⁸ Hodges 2005, p. 29.

²⁸⁹ Case C-376/98 *Germany v. Parliament and Council* [2000] ECR I-8419.

²⁹⁰ Jachia & Nikonov 2011, p. 152.

considering processed foods with multiple ingredients.²⁹¹ For socio-economic reasons, precisely such manufactured foods are what the majority for its daily food supply depends on—only very few people, by contrast, forego industrially processed food and seek to go back to nature (Jannssen and Voragen 1997).²⁹² In fact, the food industry is the single largest manufacturing sector in the EU in terms of turnover, added value and employment, and its share in the sector continues to grow.²⁹³

This widespread dissemination of foodstuff products and of their ingredients is aggravated by the fact that foodstuff risks often multiply. De Vries (1997) distinguishes health risks associated with food intake roughly into two types: toxicological ones²⁹⁴ and microbiological ones (which again have to be subdivided in risks of infection and risks of intoxication).²⁹⁵

At least microbiological risks are peculiar for foodstuff consumption goods. On the one hand, during the production, processing and packaging, foodstuffs are exposed to contaminants—particularly when being processed in a raw state.²⁹⁶ Hence, not only the contaminated ingredients themselves scatter through the ‘food matrix;’ instead, with every processing step, they also possibly pass their biological agents on other (harmless) products, where they increase a thousand-fold in a minimum of time. On the other hand, foodstuffs are subject to (bio)chemical changes, which may form potentially hazardous compounds, e.g. due to the use of additives, of preservatives, of biotechnological developments (e.g. of gene manipulation) as well as due to chemical deterioration.²⁹⁷

This also has an effect on the risk identification. Routine inspections often do not suffice to discover unsafe foodstuffs; in particular, as food can be a host for an unlimited plethora of pathogens, regular inspections can only cover fractions of agents.²⁹⁸ Food inspectors have to rely on their experience and autonomy and to make samples even in cases where a systematic evaluation of the risks in the laboratories has taken place but does not show the presumed results.²⁹⁹ For manufacturers and producers, who have to comply with the legal requirements, the situation is even worse, as they usually do not possess the knowledge and the means to discover risks; e.g. a cucumber producer will typically not be able to detect harmful pathogens.

²⁹¹ Kapur & Smith 2011, pp. 320f.

²⁹² Jannssen & Voragen 1997, p. 3.

²⁹³ Zurek 2012, p. 5.

²⁹⁴ See, e.g., Jannssen, Put & Nout 1997, pp. 8ff.

²⁹⁵ De Vries 1997, Preface; see also Jannssen, Put & Nout 1997, p. 20 or Notermans & Mead (1999), pp. 409ff.

²⁹⁶ De Vries 1997, Preface; see also Jannssen & Voragen 1997, pp. 5/6.

²⁹⁷ De Vries 1997, Preface.

²⁹⁸ Because of the intensity of emergency risks, Micklitz and Roethe (1994) plea for a concentration of product safety policy on emergencies and a downgrading of routine inspections, see Micklitz & Roethe 1994, p. 70.

²⁹⁹ Micklitz & Roethe 1994, p. 68.

This predisposition of foodstuffs heightens the likelihood of being the subject of biological terror campaigns³⁰⁰ and thus the emergency preparedness; the U.S. even believes biological terror campaigns to be one of the most dangerous weapons of mass destruction.³⁰¹ In particular, unlike other consumption goods, food is of fundamental importance to life.³⁰² Poor food safety therefore can have devastating effect.

Likewise, non-food consumption goods pass through many working steps (such as the complex machinery of cars), each of which provides great scope for new risks to occur, e.g. because of the (improper) incorporation of (further) risk-posing components. Yet, non-food risks are either toxicological or technical (e.g. product defects or malfunctions); both however, unlike pathogens, neither multiply nor encroach.³⁰³ Even toxicological substances such as plasticisers are not ‘contagious’ and thus do not spread so quickly or uncontrollably. Often, moreover, they damage consumers only in a long-term perspective when being used over a longer period or in an inappropriate manner, e.g. when children (repeatedly) put toys in their mouth (precisely like food). Compounds in foodstuff, by contrast, develop their dangerousness precisely when being used the way they are supposed to be used, namely when being ingested.

(2) A further issue resulting thereof is the traceability of food risks. Whereas damages caused by non-food risks regularly can be easily assigned to their sources, due to the quick and extensive spread, food risks often seem to be disconnected from their original source. This is aggravated by the fact that food-borne diseases usually require an incubation time from 1 to 96 hours.³⁰⁴ Therefore, the search for the source of the outbreak can be complex, time-consuming and expensive, and even after the identification, the risk regulators must either isolate the products affected or develop and prepare an antidote.³⁰⁵

Moreover, in case of non-food consumer goods, the users often are able to discover the existence of a danger themselves; whether or not the goods constitute an emergency is subject to everyday life experience (Micklitz and Roethe 1994).³⁰⁶ Traditionally, people also determined food safety through their personal experience; they knew where the food came from, where it was produced and how it

³⁰⁰ See Kapur & Smith 2011, pp. 305ff.

³⁰¹ Are we prepared? Four WMD crises that could transform U.S. security 2009, pp. 71ff; Martin, Christopher and Eitzen (2007) emphasize that already during the Peloponnesian War, biological agents were used as agents of warfare, see Martin, Christopher & Eitzen 2007, pp. 1ff.

³⁰² Jannssen & Voragen 1997, pp. 3 f.

³⁰³ Exceptions, e.g., are radiating substances.

³⁰⁴ Jannssen, Put & Nout 1997, p. 20.

³⁰⁵ Even the preparation of biological agents for mass dispersal (as a weapon) requires sophisticated laboratory and production facilities, see Kapur & Smith 2011, p. 305.

³⁰⁶ Micklitz & Roethe 1994, p. 67.

should be prepared, in order to minimize potential harmful consequences.³⁰⁷ Nowadays however, the foodstuff is traded all over the world and undergoes many production steps. For this reason, consumers have to rely on the complicated chemical testing procedures. Although they feel ill after having eaten unsafe food, they seldom know where their ill-feeling is coming from.³⁰⁸ This clearly leads to a general uncertainty, which further heightens the public anxiety.

(3) It is moreover increasingly important how the public perceives risks,³⁰⁹ as this decisively influences the political attitude. In fact, there are huge differences between the perception of food and of non-food risks.

On the one hand, consumers of course are aware of the above-mentioned peculiarities of food risks. On the other hand, the perception of food-related hazards usually does not agree with the acknowledged health risks assessed on base of accepted scientific criteria.³¹⁰ In the eyes of the public, it seems to make a huge difference whether potentially harmful risks are ‘body-internal’ or ‘body-external,’ in other words whether they cause a disease or an accident. As Zurek (2012) points out, food defines us not only physiologically but also culturally, socially and in many other ways—we even identify ourselves through our food.³¹¹ A low food quality therefore can shake our self-conception to the very foundations. We feel disgusted.³¹² Even the legislator has recognised the significance of disgust and therefore laid down that food shall not only be deemed to be unsafe if it is considered to be injurious to health, but also if it is simply ‘unfit for human consumption,’ Art. 14.2 Foodcode.

(4) The great public attention concerning food risks also results from the varying structures in the emergency management. In case of foodstuff emergencies, it is much more likely that the public takes notice. According to Micklitz and Roethe (1994), for the processing and the evaluation³¹³ of non-food risks, as well as for the subsequent determination of respective decisions, expert knowledge is the dominating factor; the processing resembles a closed system where access is limited to those who

³⁰⁷ Zurek 2012, p. 8.

³⁰⁸ Micklitz & Roethe 1994, p. 67.

³⁰⁹ De Vries 1997, Preface, Zurek 2012, p. 8.

³¹⁰ See De Vries 1997, Preface, who as an example alleges pesticide residues, whose effects concern the public, although, in fact, the risks resulting thereof are minimal; see also Jannssen, Put and Nout (1997), who refer to epidemiological data and to a survey held in the Netherlands in 1990. Alemanno (2008) describes this phenomenon of ‘manufactured’ risks as an attribute of the modern ‘risk society,’ see Ibid, JMWP 18/08, p. 5, with reference to the sociological concept of Ulrich Beck; Alemanno does not distinguish between food and non-food risks however.

³¹¹ Zurek 2012, p. 1.

³¹² See, e.g., so-called Birkel-Case, Decision by the OLG Stuttgart (Higher Regional Court) of 21 March 1990, 1 U 132/89, NJW 1990, 2690, which addressed the mistakable depiction of the use of disgusting liquid eggs during the production of pasta.

³¹³ Processing means the organisational, informational and consultative preparations, see Micklitz & Roethe 1994, p. 51: (1.) notification, (2.) processing, (3.) evaluation and decision, (4.) warning the public at large.

belong to the guild of experts.³¹⁴ In the processing of food risks, by contrast, risk managers and political decision-makers have to be brought together, meaning that the different levels of competences have to be combined,³¹⁵ which attracts much more public attention.

The foodstuff test results finally gain societal importance only if the decision-makers interpret them as a source of action,³¹⁶ which they usually do in consequence of a mutual exchange between society, experts and decision-makers.

(5) In conclusion, food risks have huge potential to fulfil all prerequisites of an emergency. Firstly, they often have potentially widespread and severe consequences and for this reason require rapid intervention. Secondly, they often attract public attention. Thirdly, since they usually gain public attention only after the first damages have occurred (beforehand, they are very difficult to spot), they usually are evident. In particular, well-being damages occur much more quickly than health damages do.

³¹⁴ Micklitz & Roethe 1994, pp. 51/52.

³¹⁵ Micklitz & Roethe 1994, pp. 51/52.

³¹⁶ Micklitz & Roethe 1994, pp. 51/52.

5. Hypotheses revised

Although European product safety at first glance may suggest to mainly serving the consumer protection, in fact, it primarily aims to set a ceiling for any ‘over-protection’ that could hinder the internal market. This also holds true for foodstuff risks, which nonetheless must be well-controlled, as they, being predisposed to become serious and to outrage the public, have the potential to particularly harm the internal market. The secondary legislation manages to cope with these requirements only to a limited extent.

In times, where the European Union brags about having developed from a mere economic community to a community of (shared) values, this superiority of the internal market appears retrograde and dishonest. It is a vestige of an earlier regime. The peace-saving function of the trade community is far from being the only purpose of the European Union anymore. Nevertheless, the current regulation of the co-existence of Member State and EU competences leads to a misbalance of economy and other values. Whenever the EU sets standards, these must be focussed on the internal market, as other competences are barely provided; for this reason, even when the EU claims the power from the Member States to deal with food risk emergencies, this is supposed to ensure that the internal market remains priority number one. This misbalance creates discord between the actors, as has happened in the E. coli bacteria crisis, and upsets regulators and judges, which are caught between two stools. In particular, however, it gives the consumers reason always to question the EU policies.

For the future, a thorough revision of the competence division between the European Union and the Member States is desirable, particularly as the *status quo* seems to be an interim stage between two ideas of a European Union. Such a development, however, cannot be achieved overnight. As Giorgio Napolitano has stated (as President of the Italian Republic),

“Speaking from my experience as a person involved for a long time in building the European Union, it is important to have patience and efforts to build a community of nations.”

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7. Annex: Proceedings in the two cases

- a. The case of the vehicle lifts –
ECJ Case C-470/03: *A.G.M.-COS.MET Sri v Suomen valito/Tanno Lehtinen*³¹⁷

The Italian company A.G.M. produced and sold various types of vehicle lifts with similar constructions, which then were imported to Finland by the Finnish company Pörhön Tuontiliike. In 1997, an authorised Italian company certified the type AGM G 35 of the vehicle lifts as complying with the old Machinery Directive³¹⁸ and the lifts were granted the CE marking.³¹⁹ The operating instructions stated that the vehicle had to be driven between the columns in such a way that the higher axle weight was borne by the short arms, and the lower by the long arms.³²⁰

On 11 May 2000, the Ministry of Social Affairs and Health in Finland received a market supervision report issued by the Vaasa health and safety district office³²¹ that with regard to type AGM G 35 T/E deficiencies had been detected, in particular firstly, a bending of the front lifting arms and secondly, a weak locking of the lifts. For that reason, the report advised the Ministry to restrict or even prohibit the sale and use of the vehicle lifts.³²² Mr. Lehtinen, chief engineer and official of the Ministry of Social Affairs and Health, subsequently, drafted a report about the safety defects, in which he shared the concerns of the authority in Vaasa. He argued that the standard in question, SFS-EN 1493, required a structure of the system that could bear the maximum permitted load even in the least favourable lifting conditions and regardless of the direction in which the vehicle was driven onto the lift. A test performed on 27 November 2000, however, had demonstrated the non-compliance of the vehicle lifts with these requirements. Moreover, Lehtinen criticized the safety of the locking system. Due to the disclosed defects, therefore, also the official asked the Ministry to restrict or even prohibit the sale and use as quickly as possible. In response, A.G.M. proposed a new locking system for the vehicle lifts. Although, after a test on 12 December 2000, Mr. Lehtinen in a memorandum confirmed that the new locking system had performed better and that now the system's resistance had been found adequate, the official repeated his previous observations: when loaded at the maximum and driven onto the least

³¹⁷ Case C-470/03, Judgment of the Court of 17 April 2007, *AGM-COS.MET v Suomen valito/Tanno Lehtinen* [2007] E.C.R. I-2749.

³¹⁸ Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery, OJ L 207, 23.7.1998 [hereinafter referred to as old MD]; replaced by Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) OJ No L 157, 9 June 2006 [hereinafter referred to as MD].

³¹⁹ See Opinion of Advocate General Kokott in *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03) [2007] E.C.R. I-02749, para. 26.

³²⁰ *Ibid.*, para. 25.

³²¹ According to the German translation of the judgement, a Finnish authority responsible for the protection of workers, see *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03), para. 21.

³²² See Opinion of Advocate General Kokott in *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03), para. 29.

favourable direction, the lift still showed defects. In a third report on 12 February 2001, he extended his concerns also to the models G 28 and G 32.³²³

With the knowledge of the Ministry, on 17 January 2001, Mr. Lehtinen and a representative of the importer both were interviewed by a national television channel. Upon inquiry of the presenter, the importer's representative admitted that the locking system was defective, declared however that the vehicle lifts could bear any weight if the vehicle was driven onto the lift in the correct direction. Mr. Lehtinen, on the other hand, stated that the vehicle lifts presented an immediate danger for the workers beneath the load and that the certification body chosen by A.G.M. had misinterpreted the provisions. Soon after, also the Association of Technical Trades reported the Ministry serious defects allegedly found in machinery of A.G.M. Nevertheless, on 8 February 2001, Mr. Hurmalainen faxed the representative of the Central Association of Industry and Employers that he opposed a ban of the vehicle lifts. In fact, only one accident had occurred in Finland—for reasons unknown; thus, to him the adoption of measures that could disturb the working of the internal market seemed unreasonable. Mainly because Mr. Lehtinen had opposed the Ministerial instructions by expressing a point of view differing from the official position, on 16 February 2001, Mr. Hurmalainen removed him from dealing with cases concerning the vehicle lifts by A.G.M. In a subsequent report, the health and safety division of the Ministry accused Mr. Lehtinen of breaking the principle of sound administration and collaborating with A.G.M.'s competitors.

Subsequently, an article about the dangerousness of the vehicle lifts based on an interview with Mr. Lehtinen was published. Moreover, in a memorandum, also the Metalworkers' Union maintained that the vehicle lift in question had 'indisputably been shown to be dangerous.'³²⁴ Regardless of the several reports on serious doubts about the safety, however, on 14 June 2001, the health and safety division of the Ministry decided that by that time no factors had emerged obliging the Ministry to the adoption of measures against the manufacturer or the importer of the lifts. In October, Mr. Lehtinen eventually received a written warning under the Law on State officials for breaching his obligations as an official by continuing to give a misleading picture even after the case had been withdrawn from him on 16 February 2001.

When the company A.G.M. finally claimed compensation from the Finnish State as well as from Mr. Lehtinen for the damage caused to its business,³²⁵ the Tampere District Court referred to the Court

³²³ See Opinion of Advocate General Kokott in *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03), para. 36.

³²⁴ *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03), para. 32.

³²⁵ According to A.G.M., the collapse in profit alone was about 300 000 € in 2001 and about 750 000 € in 2002, see Opinion of Advocate General Kokott in *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03), para. 45.

of Justice a number of questions on interpretation of the rules on the free movement of goods and on the conditions of liability for infringement of Community law. In particular, it raised the question whether Mr. Lehtinen's conduct as a measure having equivalent effect to quantitative restrictions had transgressed the free movement of goods.

The Court of Justice found that Mr. Lehtinen's conduct had violated Art. 4.1 old Machinery Directive. Opinions expressed by an official could be attributed to the Member State itself, if their form and circumstances gave the persons to whom they were addressed the reasonable impression that they were pronouncements of the State, taken with the authority of the official's office, and not his personal opinions.³²⁶ This applied to Mr. Lehtinen's utterances, so that they could be assigned to the Finnish State. As regards the breach of the free movement of goods, referring to Art. 4.1 old MD (Art. 6.1 MD), the Court declared that if, as in the present case, a matter was subject of exhaustive harmonisation at Community level, the latter was the benchmark, not primary law, such as Art. 34 AEUV (ex-Art. 28 EC); hence, the proceedings in the present case had to be assessed on base of the Machinery Directive. Because of the CE marking, Art. 5.1 old MD (Art. 7.1 MD) presumed the compliance of the vehicle lifts. Despite this presumption, indeed, the Member States were obliged to adopt appropriate measures to withdraw machinery from the market, if they ascertained that the latter posed a danger, see Art. 7.1 (Art. 11.1 MD). In the case of the vehicle lifts, however, the competent authorities had not ascertained any risk nor taken measures to withdraw the machines. The conformity thus had to be presumed and possible obstacles for the internal market to be removed. In conclusion, the statement, which was attributable to the State and described certified machinery as contrary to the legal standard and dangerous, constituted a breach of Art. 4.1 old MD.

The Court moreover dismissed any justification for the statements in question both on grounds of freedom of expression and of health protection. The freedom of expression (Art. 10 ECHR) of officials could not be plead by the Member States to justify obstacles to the free movement, as they so evaded their liability.³²⁷ The consideration of health protecting aspects was conclusively regulated in the Directive, in particular in Art. 7.1 old MD.³²⁸

As a last point, the Court referred to its own conditions on liability for infringement of Community law and found that any additional condition in the law of the Member State that would make it excessively difficult to obtain compensation would be permitted.

After the ECJ judgment, the case was settled by the parties in the Tampere District Court.

³²⁶ *AGM-COS.MET v Suomen valito/Tanno Lehtinen* (C-470/03), para. 57.

³²⁷ *Ibid.*, para 72.

³²⁸ *Ibid.*, para 68.

b. The E. coli bacteria crisis in 2011

In the E. coli bacteria crisis in 2011, the German authorities publicly warned *inter alia* against Spanish cucumbers, which they falsely supposed to be contaminated with E. coli bacteria serotype O104:H4. The financial damage of this warning was immense; vegetable producers all over Europe immediately suffered heavy losses in sales. Consequently, almost from the very beginning of the outbreak, farmers, media and governments criticised the German authorities for a lack of coordination and accused them to issue wrong warnings prematurely, while the German government only stood on the sidelines.³²⁹

In winter 2008/09, a company in Lower Saxony (Germany) imported fenugreek seeds from Egypt to Germany for its sprout production, without knowing, however, that the seeds were contaminated with *Shiga Toxin-producing Escherichia coli* (STEC) bacteria, serotype O104:H4.³³⁰ From 8 May 2011 on, several cases of STEC-infected human beings occurred in Northern Germany. The ill people complained about initially watery and later bloody diarrhoea, abdominal pain, nausea, vomiting and in some cases about fever. The outbreak reached its peak on 22 May 2011 and ended on 25 July 2011.³³¹ During this period, throughout Germany, 3842 cases of infected persons were reported to the Robert Koch Institute (RKI); 855 cases of that were affected with the hemolytic-uremic syndrome (HUS), a severe complication of E. coli disease, which is characterized by kidney failure, impaired blood clotting and a destruction of the red blood cells; fifty-three patients died.³³²

On the peak of the outbreak on 22 May 2011, the German health services as well as the Commission launched alert systems at local, national, EU and international level.³³³ The German authorities sent a team of experts from the RKI to a restaurant in Hamburg to undertake further investigations and notified the EU of the ongoing outbreak by issuing a confidential EWRS report. In the report, they informed the Union that both milk and meat had been ruled out as potential sources for the outbreak and that the experts had started to focus on raw vegetables. To discuss the evolution of the outbreak and possible measures, the Commission convened daily meetings with the national public health and food safety authorities of the Member States and the relevant European risk assessment agencies, namely the European Food Safety Authority (EFSA), the European Centre for Disease Prevention and Control (ECDC), the European Reference Laboratory (EU-RL) for E. coli bacteria and the Directorate-General for Health and Consumers (DG SANCO).³³⁴ In addition, the Health Security

³²⁹ See, e.g., Kritik am Ehec-Krisenmanagement der Regierung 2011 or EHEC: Spanien beklagt Produktionsausfälle und prüft Schadenersatzanspruch 2011.

³³⁰ EHEC-Ausbruch 2011.

³³¹ Technical Report 30 June 2011.

³³² Effective 16 August 2011, see EHEC/HUS-Ausbruch in Norddeutschland 2011.

³³³ Commission Staff Working Document Lessons learned, 2011.

³³⁴ Flash Report of the European Commission 2011.

Committee (HSC) discussed possible responses to the outbreak.³³⁵ According to the Coga-Cogeca working group, within the first two weeks of the crisis, the farmers in the fruit and vegetable sector lost more than 812 Mio. €. ³³⁶

Since the affected persons had consumed these vegetables increasingly, on 25 May 2011, the German RKI and the Public Health Authority Hamburg publicly warned against raw tomatoes, cucumbers and leaf salad from Northern Germany. It was not clear yet ‘whether only one or all three foods were related to the outbreak;’ based on a study, however, they recommended as a precaution not to consume any of them in a raw state.³³⁷ Shortly afterwards, the RKI succeeded in identifying the specific serotype O104:H4.³³⁸ The authority for Health and Consumer Protection Hamburg isolated E. coli bacteria on two samples of cucumbers originating from Spain,³³⁹ whereupon the Health Senator of Hamburg Cornelia Prüfer-Storcks announced, “We have found the source;”³⁴⁰ however, it turned out that the serotypes were not identical.

In a next audio-conference with the European bodies and the representatives of the Member States on 26 May 2011, the ECDC declared that the source was still unknown, although cucumbers might be one source, as 88 % of the persons affected had consumed them.³⁴¹ The tested cucumbers from Spain and the Netherlands had not belonged to the same sample. The participants of the conference requested a formal case definition of the pathogen in English and the RKI advised the bodies to be cautious about communicating cucumbers from the Netherlands or Spain as a risk. On the following day, Germany and the Commission issued general warnings concerning cucumbers from Spain in the RASFF portal.³⁴² The Commission also published a press release on its website that according to the German authorities, cucumbers were a possible source.³⁴³

In the audio-conference on 27 May 2011, the RKI mistakenly declared cucumbers from Malaga and Almeria as tested positive on the particular serotype; however, the Institute corrected its statement in the conference on 30 May 2011; the results were still pending. The ECDC agreed with the RKI that, even though not finally confirmed yet, raw tomatoes, fresh cucumbers and leafy salad were likely vehicles of the infection. Meanwhile, in its examinations, the RKI kept on finding vegetables

³³⁵ See, e.g., Health Security Committee 2014.

³³⁶ Commission Staff Working Document Lessons learned 2011, with reference to an estimate made by the COPA-COGECA working group (two organisations representing European farmers).

³³⁷ Joint Opinion of the Federal Institute for Risk Assessment and the RKI of 25 May 2011.

³³⁸ EHEC-Gurken - Spanien wehrt sich 2011.

³³⁹ ECDC Rapid Risk Assessment 2011.

³⁴⁰ EHEC-Gurken - Spanien wehrt sich 2011.

³⁴¹ Audio-conference 26 May 2011.

³⁴² RASFF notification against Spanish cucumbers 2011.

³⁴³ EHEC: Kommission informiert über mögliche Quelle 2011.

positive for *E. coli* bacteria, however, not for the specific serotype.³⁴⁴ On 01 June 2011, the Commission and Germany withdrew their alerts on cucumbers, as the specific serotype had not been detected. Nevertheless, the RKI, the German Federal Institute for Risk Assessment and the Commission maintained their press releases on the websites warning against tomatoes, cucumbers and lettuce.³⁴⁵

On 02 June 2011, Russia imposed an import ban on all EU vegetables and preserved this ban for the next two months.³⁴⁶ In a statement in Brussels, John Dalli, Commissioner for Health and Consumer Policy, prompted the Member States, especially Germany, to increase their efforts. He also suggested sending an EU team of experts to Germany to support the investigations.³⁴⁷ On 5 June, with the consent of the German authorities, the Commission, ECDC and EFSA sent a team of seven experts to Berlin.³⁴⁸

On 07 June 2011, due to a sample taken from a sprout producer in Lower Saxony, Germany issued a RASFF notification saying that an organic sprouts mixture from Germany was suspected to be contaminated with STEC bacteria.³⁴⁹ In the audio-conference, the EU Laboratory for *E. coli* bacteria and Spain asked the German Federal Institute for Risk Assessment to share its methods used for the sampling of the sprouts.³⁵⁰ The Commission, furthermore, requested the German representative to provide information about a press report saying that suspicious German meat was examined in the Czech Republic; since RASFF notifications ensured the traceability of products, it asked Germany to use the official channels.

The next day, the German Federal Institute, the German Federal Office of Consumer Protection and Food Safety and the RKI publicly warned against the consumption of sprouts.³⁵¹ Only then, the German authorities withdrew their recommendation to avoid the consumption of raw tomatoes, cucumbers and leaf lettuce. The Commission launched promotion activities and a media campaign to rebuild the trust of consumers in fruits and vegetables.³⁵² On 25 June 2011, France issued a RASFF notification saying that fenugreek seeds imported for sprouting from Egypt (packaged in the United Kingdom, via the Netherlands and via Germany) were suspected to have caused the outbreak that was

³⁴⁴ Audio-conference 27 May 2011.

³⁴⁵ Neue epidemiologische Daten untermauern bisherige Verzehrsempfehlung des BfR 2011.

³⁴⁶ Russisches Importverbot von Gemüse erzürnt die EU 2011.

³⁴⁷ See, e.g., EU will EHEC-Experten nach Deutschland schicken 2011.

³⁴⁸ Escherichia coli outbreak in Germany 2011.

³⁴⁹ RASFF notification against organic sprout mixture 2011.

³⁵⁰ Audio-conference 07 June 2011.

³⁵¹ Technical Report 30 June 2011.

³⁵² Commission Staff Working Document Lessons learned 2011.

triggered by STEC bacteria type O104:H4.³⁵³ The EFSA confirmed the source on 06 July 2011, whereupon the Commission temporarily banned sprout seeds from Egypt.³⁵⁴

³⁵³ RASFF notification against fenugreek seeds 2011.

³⁵⁴ Schutz vor EHEC 2011.